IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01362
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, et al., Defendants.	Civil Action No. 3:17-01665

MEMORANDUM IN SUPPORT OF
CARDINAL HEALTH'S MOTION FOR JUDGMENT

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INTRODUCTION

Plaintiffs' proof as to Cardinal Health fails on three fronts.

First, Plaintiffs have failed to prove that, by its conduct in developing and implementing a suspicious-order monitoring system, Cardinal Health acted unreasonably. Only one witness (James Rafalski) purported to have evaluated that system, and his methodologies were so clearly invented for purposes of the litigation, and his opinions were so divorced from hard facts, that the Court should exclude his testimony. Even if admitted, however, his testimony is deserving of no weight, for Rafalski did not identify: (1) one pharmacy customer that Cardinal Health should not have approved in the first place (or later should have terminated); (2) one pill that the company distributed outside the "closed system" (i.e., to anyone other than a state-licensed, DEA-registered pharmacy); (3) one pill that any of the company's pharmacy customers diverted or dispensed without a doctor's prescription; (4) one prescription dispensed by any of the company's pharmacy customers that was not written for a legitimate medical purpose; or (5) one criticism of the Wheeling Distribution Center (the Center that supplied Cabell/Huntington pharmacies) by the DEA or state regulators. On the other hand, Michael Mone—a lawyer, pharmacist, and former regulator—offered detailed and credible testimony about (1) the modifications made to Cardinal Health's system to comply with the DEA's new interpretation of the anti-diversion regulations; (2) his thorough presentation of those modifications to the DEA; and (3) the fact that his team conducted diligence regarding every flagged order. After requiring Cardinal Health to bring him to Charleston to testify, Plaintiffs declined to call Todd Cameron, Mone's successor, and presented no evidence about the period after 2012.

Second, Plaintiffs have failed to prove that Cardinal Health's conduct caused the harm alleged. The evidence has made plain what before was abstract—that individual addiction (much

less the interference with a public right purportedly resulting from that addiction) is many steps removed from distribution, and that those intervening steps involve medical and professional judgments and layers of illegal activity that eliminate any possibility of legal "proximity" between Cardinal Health's conduct and Plaintiffs' harm. Even more fundamentally, Plaintiffs have failed to prove cause-in-fact. There is no evidence—***none***—that: (1) had Cardinal Health conducted more or different due diligence, it would have had reason to block more orders, (2) had it blocked more orders, the pharmacy customers would not have obtained the prescription opioids from other distributors, or (3) had it reported more orders as suspicious, the DEA would have undertaken any enforcement activity that would have reduced the volume of opioids prescribed in Cabell/Huntington.

Third, Plaintiffs have failed to show that the Court can award the sought-after relief. Supreme Court precedent is clear in three relevant respects.

First, a federal court sitting in equity, as Plaintiffs have requested this Court do, cannot afford equitable relief if an adequate remedy exists at law. Such a remedy does exist here. Plaintiffs alleged a legal remedy and defended its validity when challenged. That they have disclaimed damages does not mean that an adequate legal remedy does not exist and it does not give the Court authority to grant equitable relief.

Second, a federal court in equity can only award monetary relief that is adjunct to injunctive relief. Despite repeated opportunities, Plaintiffs have failed to cite the example of any federal court that has ever awarded equitable relief of the kind they seek here.

Third, a federal court must narrowly tailor equitable relief to match the relief to the wrong. Plaintiffs' abatement plan manifestly fails to do that—most notably in proposing that Cardinal Health pay for addiction treatment and related services and programs for

Cabell/Huntington residents who never used a prescription opioid and are not now addicted and may only become so sometime in the next 15 years. The evidence, however, does not permit the Court to segregate the relief that might be attributable to Cardinal Health's past conduct from the relief designed to address future harm that has no connection to the company's conduct.

For these reasons, as explained below and documented from the record, the Court should grant judgment in favor of Cardinal Health.[1]

I. PLAINTIFFS FAILED TO PROVE THAT CARDINAL HEALTH UNREASONABLY INTERFERED WITH A PUBLIC RIGHT

Plaintiffs failed to prove that Cardinal Health acted unreasonably in its distribution of prescription opioids to Cabell/Huntington. Indeed, the evidence presented in Plaintiffs' case establishes that Cardinal Heath acted reasonably, both before 2007, when the DEA approved and accepted the industry-wide reporting of excessive orders (including orders that were reported after they were shipped), and after 2007, when the company blocked suspicious orders and fully implemented the three components of the DEA-sponsored AmerisourceBergen suspicious-order monitoring system.[2]

The failure of proof is evident on many levels. The opening statement by Plaintiffs' counsel was noteworthy for its failure even to promise proof of wrongful conduct. Declaring that the "first pillar" of their case is volume, Plaintiffs manifested a belief that it would be sufficient to prove that Cardinal Health (along with AmerisourceBergen and McKesson) "sold a

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[1] Plaintiffs' burden is to prove the liability of each Defendant. Cardinal Health files this separate brief to underscore that burden, not to disapprove any argument made by AmerisourceBergen and McKesson, whose memoranda in support of their separate motions for judgment Cardinal Health adopts and incorporates by reference.

[2] Cardinal Health continues to assert that claims for conduct that occurred prior to January (City of Huntington) or March (Cabell County) 2016 are time-barred, Dkt. 241, 356, but for purposes of Part I, we assume that there is no statute-of-limitations bar to claims for conduct occurring before January 2016.

mountain of opium [*sic*] pills into our community fueling the modern opioid epidemic."[3] With one exception, Plaintiffs' witnesses in the days that followed alternated between those who testified regarding the volume of opioids prescribed, dispensed, and distributed to the community and those who testified regarding the harm experienced by the community as a result of addiction. And now we have come full circle, Plaintiffs' counsel pointing solely to the volume of pills as the proof of unreasonable conduct "What we would say is the measurement of whether or not their conduct was reasonable can be determined by looking at the volume of pills they sold…."[4]

At the end of the day, there is ***no evidence*** that Cardinal Health ever distributed prescription opioids other than to a licensed pharmacy. There is ***no evidence*** that a pharmacy customer of Cardinal Health dispensed opioids other than to fill a doctor's prescription. There is evidence that only four Cabell/Huntington doctors out of the more than 500 (on average) who prescribed opioids did so other than for a legitimate medical purpose.[5] And the evidence ties only ***one*** of the four doctors to prescriptions filled by a Cardinal pharmacy customer (his prescriptions accounted for just 0.2 percent of prescriptions filled by that pharmacy).[6] Finally, there is ***no evidence*** that any of Cardinal Health's pharmacy customers diverted opioids—or, indeed that the opioids dispensed by those pharmacies were diverted. The only testimony about diversion concerned the general pathways by which it occurs (e.g., "medicine cabinet"

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3 Tr. (May 3) at 11. All references to "Tr." are to the trial transcript.

4 Tr. (July 1) at 105.

5 No witness testified that these four doctors (or any Cabell/Huntington doctors) prescribed opioids contrary to the prevailing standard of care. Dr. Keller, who declined to offer such an opinion, Tr. (May 15) at 168–70, testified that the four doctors were disciplined by the Board of Medicine, *id*. at 136, 142, 182, 233.

6 *See* n. 57, *infra.*

diversion), and which take place after the medications leave the control of both Cardinal Health and its pharmacy customer.[7]

Only Plaintiffs' expert, James Rafalski, testified specifically about Cardinal Health's conduct. But he employed a set of methodologies and tendered a set of *ipse dixit* opinions that warrant striking his testimony under Rule 702 and *Daubert*. Even if his testimony survives Rule 702/*Daubert* review, however, it is so heedless of historical context and common sense, so lacking in specifics as to which pharmacy orders should have been blocked and why, and so conclusory in the opinions expressed that it is entitled to no weight. Absent Rafalski's testimony, whether stricken or discounted, there is no evidence that Cardinal Health acted unreasonably.[8]

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[7] Tr. (May 4) (Waller) at 174–75 (diversion of unused opioid pills occurs between friends and family members); Tr. (May 6) (Gupta) at 91 (over-prescribed pills went unused and were diverted from patients' medicine cabinets); Tr. (May 26) (Rafalski) at 199 (no disagreement that "[m]ore than three out of four people who misuse prescription pain-killers use drugs prescribed to someone else"); Tr. (June 9) (Rannazzisi) at 141 (gave presentation that most frequent method of obtaining a controlled substance for non-medical use was through friends and family); Trial Ex. MC-WV-02079 (Compton 2019) (more than half of those who misuse prescription opioids obtain them from friends or family members who have prescriptions).

[8] We respectfully submit that the Court misread *Hendricks v. Stalnaker*, 380 S.E.2d 198 (W. Va. 1989), in its Memorandum Opinion and Order denying Defendants' motion for summary judgment regarding fault, Dkt. 1294, and that the proper test of wrongfulness for purposes of a public nuisance claim is whether the conduct is (i) intentional and unreasonable, (ii) negligent or reckless or (iii) results in abnormally dangerous conditions or activities in an inappropriate place. We explain why Plaintiffs must meet the first prong of this test in Appendix A. For purposes of this Memorandum, we assume (as the Court held in Dkt. 1294) that Plaintiffs must prove only that Cardinal Health's conduct was unreasonable.

Cardinal Health adopts Part II, AmerisourceBergen Drug Corporation's Memorandum in Support of Motion For Judgment Under Rule 52(c) Based on Plaintiffs' Failure to Prove Culpable Conduct. Dkt. 1443-1.

A. Rafalski's Testimony Is Not Entitled to Any Weight

For the reasons already given,[9] the Court should grant Defendants' motion to exclude Rafalski's testimony. Absent his expert testimony, Plaintiffs cannot prove fault. No other witness evaluated Cardinal Health's suspicious-order monitoring system (at any stage), and no other witness opined that it was deficient. Likewise, no other witness reviewed Cardinal Health's due diligence files for any Cabell/Huntington pharmacy customer. And no other witness opined that the company approved a pharmacy as a new customer it should not have, or failed to terminate a customer it should have, or cleared an order for shipment to a Cabell/Huntington pharmacy that it should have blocked.

But even if the Court does not exclude Rafalski's testimony, it should accord his testimony no weight for the following three reasons.

1. Rafalski's opinions are heedless of context and common sense

At the prompting of Plaintiffs' counsel, Rafalski closed his direct testimony by giving three naked opinions regarding each Defendant—that (1) it did not maintain effective controls to prevent diversion of prescription opioids in Cabell/Huntington; (2) it did not operate an effective system to identify, block, and report suspicious orders; and (3) the failure was systemic.[10] As to Cardinal Health, the three opinions were devoid of explanation and unconnected to evidence that (i) Cardinal Health distributed a single pill to anyone other than a licensed pharmacy (i.e., outside the "closed system"), or that a single order placed by any pharmacy customer (ii) was diverted by the pharmacy itself or (iii) was dispensed other than to fill a legitimate medical prescription.

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[9] *See* Dkts. 1386, 1398, 1405.

[10] Tr. (May 26) at 108–09.

The sole "evidence" supporting Rafalski's three opinions is the facially dubious application of his Methods A and B, which labeled between 66 and 93 percent of pharmacy orders as suspicious and warranting inquiry.[11] But that "evidence" ignores completely the larger context in which pharmacies were placing orders for prescription opioids. The supply of medications by wholesale distributors does not drive demand. As Rannazzisi readily admitted, the opposite is true: demand for prescription drugs drives supply.[12] Doctors write prescriptions; pharmacies dispense the medications and order more to replenish their depleted inventory; and only then do distributors act to supply the pharmacies. The record evidence is overwhelming that pharmacy orders for prescription opioids increased from the 1990s through the 2000s because Cabell/Huntington doctors prescribed more and more opioids. They prescribed more opioids per capita than doctors in other parts of the country, just as they prescribed more of almost all medications.[13] They did so because, as Plaintiffs alleged and as the evidence overwhelmingly established, the standard of care for prescribing opioids changed. Where once doctors prescribed opioids for acute or terminal pain, and only as a last resort, doctors in the 1990s began to prescribe opioids for a range of conditions, including chronic pain, and often as a first-line treatment.[14] Professional medical societies issued treatment guidelines that reflected the new standard of care.[15] The Joint Commission on Accreditation of Healthcare Organizations

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[11] *Id*. at 225 (Q. … You would not use methods C through F, correct? A. If I owned a company, a distributor, and I was going to design a suspicious order system, … that's correct, I would not use those.").

[12] Tr. (June 9) at 88 ("Supply does not drive demand.").

[13] Tr. (May 6) (Gupta) at 32–33. That said, the approximately ten-fold increase in opioid distributions to Cabell/Huntington from 1997 to 2010 was the same as the increase for the State as a whole and for the nation. Tr. (May 12) (McCann) at 48–49.

[14] Third Amended Compl. (hereinafter TAC) ¶¶ 317–19.

[15] TAC ¶¶ 410, 443, 463–66.

conditioned accreditation on treating pain as the "Fifth Vital Sign."[16] The Federation of State Medical Boards itself issued such guidelines and distributed more than 160,000 copies of the book, *Responsible Opioid Prescribing*, which endorsed the guidelines.[17] The DEA expressly endorsed the FSMB guidelines:

> The DEA testified in support of the Federation of State Medical Boards' *Model Guidelines for the Use of Controlled Substances in the Treatment of Pain* in March 1998. The ***DEA endorsed the guidelines*** because they are consistent with the four cornerstones of the DEA's pain management position referred to earlier.
>
> ***The guidelines embody a reasonable approach*** to help maintain the delicate balance between preventing controlled substance diversion and ensuring access by legitimate patients.[18]

The West Virginia Board of Medicine made a point of communicating this new way of thinking about, and prescribing opioids, to all West Virginia doctors. It provided a copy of *Responsible Opioid Prescribing* to every doctor in the state.[19] And it issued policy statements to all West Virginia doctors in 1997 and 2005 that advised that prescription opioids may be

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[16] Trial Ex. MC-WV-02079 (Compton 2019) at 5; Tr. (May 21) (Werthammer) at 27 ("during that period where pain was considered the fifth vital sign, … opioids [were] prescribed more liberally"); Tr. (May 4) (Waller) at 96-97; Tr. (June 16) (Yingling) at 182 (agreeing that "the addition of pain as the fifth vital sign and the smiley face/happy face diagram shown to patients had the effect of increasing net prescribing of pain medications"); *see also* TAC ¶ 410.

[17] TAC ¶ 444. The DEA knew about the book and did not seek to correct any statements made by the author. Tr. (June 9) (Rannazzisi) at 148, 150.

[18] https://web.archive.org/web/20011205021713/http://www.*dea*diversion.*usdoj*.gov/pubs/nwslttr/spec2001/page10.htm; *see also* Tr. (June 9) (Rannazzisi) at 150 (DEA "relied on guidelines from the" FSMB). The Court can take judicial notice of the DEA's publicly posted rationale for its Congressional testimony. *Jacobus v. Huerta*, 2013 WL 673233, at *7 n.8 (S.D.W. Va. Feb. 22, 2013), *report and recommendation adopted*, 2013 WL 1723631 (S.D.W. Va. Apr. 22, 2013), *aff'd*, 540 F. App'x 208 (4th Cir. 2013) ("The court may take judicial notice of factual information located in postings on governmental websites.")

All emphases in the Memorandum are added unless otherwise indicated.

[19] The book endorsed the treatment of pain as the Fifth Vital Sign, a practice that affected opioid prescribing. Tr. (May 4) (Waller) at 97.

"essential" to the treatment of chronic, non-malignant pain and that doctors who prescribed opioids, even in large doses, should not fear disciplinary action by the Board.[20]

It is this broadly accepted change in the standard of care that explains the DEA's year-after-year increases in the annual quota, its endorsement of the FSMB guidelines, and its testimony to Congress that, even as prescriptions steadily increased, 99 percent of doctors were at all times prescribing opioids for a legitimate medical purpose.[21] Rafalski did not dispute these facts. Indeed, he admitted on cross-examination that "the ***overwhelming majority*** of physicians who prescribe controlled substances do so in a legitimate manner that will ***never warrant scrutiny*** by federal or state law enforcement officials."[22] His opinion that Cardinal Health failed to block and report suspicious orders, however, is oblivious to the "dramatic shift" in the

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[20] *Id.* at 150, 156–58; Trial Ex. MC-WV-01219 (1997 Position Statement by the West Virginia Board of Medicine stating that "opioids are appropriate treatment for chronic non-malignant pain in selected patients"); Trial Ex. MC-WV-01218 (2005 West Virginia Board of Medicine Guidelines stating that "controlled substances including opioid analgesics may be essential in the treatment of acute pain … and chronic pain, whether due to cancer or non-cancer origins).

[21] Tr. (June 8) (Rannazzisi) at 197, 199 ("if more prescriptions were going out to pharmacies, if more patients in hospitals were getting more drug, that quota was going to increase because we have to meet the needs of the patient population"); *id*. at 200 ("[y]ou can't just lower quota"); Tr. (June 9) (Rannazzisi) at 99–100 ("We generally used 99 percent, but we've gone to .5.").

[22] Tr. (May 26) at 121; *id*. at 122 (no basis to disagree with Congressional testimony of Rannazzisi that 99 percent of doctors prescribe opioids for legitimate medical purposes); Tr. (May 4) (Waller) at 104 (doctors who prescribed for chronic pain "were acting in good faith"); Tr. (May 6) (Gupta) at 93–94 ("there were more good doctors than bad doctors [in West Virginia]" and "[t]heir intent was to help their patient"); Tr. (June 14) (Keyes) at 71, 76 (agreeing that "the overwhelming majority of doctors prescribe opioids to their patients in good faith").

Moreover, the small percentage of doctors who did not prescribe opioids in good faith "do not explain in any significant way the expansion of opioid prescribing and opioid-related harm in the U.S." Tr. (June 14) (Keyes) at 131.

standard of care that led to the increased prescribing of opioids.[23] Only with blinders on could Rafalski opine on direct examination that more than 90 percent of Cabell/Huntington pharmacy orders should have been deemed "suspicious" and investigated, then on cross-examination agree that "the overwhelming majority of American physicians who prescribe controlled substances do so for a legitimate medical purpose" and "in a legitimate manner that will never warrant scrutiny" by the DEA.[24]

His knowing failure to consider the historical context in which opioid prescriptions rose reflects a partisan bias that warrants rejection of his testimony. Given his recognition that the vast majority of opioid prescriptions were legitimate and did not warrant scrutiny, his opinion that 90 percent or more of pharmacy orders should have been treated as suspicious also simply defies common sense. That opinion is also totally at odds with his recognition that the DEA could not just cut the opioid quota or impose arbitrary limits because "you might also keep it from people who need it."[25] His failure to reconcile the two is further reason to afford his opinions no weight.

2. Rafalski's opinions are conclusory

Rafalski's opinions were wholly unsupported by facts about specific Cabell/Huntington doctors who may have mis-prescribed opioids, specific pharmacies who may have filled

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[23] TAC ¶ 15 (describing "dramatic shift in how and when opioids are prescribed by the medical community and used by patients"); *id.* ¶ 375 ("by the mid-2000s, the medical community had abandoned its prior caution, and opioids were entrenched as an appropriate—and often the first—treatment for chronic pain conditions").

[24] Tr. (May 26) at 120–21.

[25] *Id.* at 183; Tr. (June 8) (Rannazzisi) at 200–01 ("You can't just lower quota. … If you have 100 people and all of those people are trying to get oxycodone and some of them are, are drug seekers who shouldn't have it and some of them are legitimate patients that need it … the quota is established so they will get their drug. … I can't do anything about the people who are seeking drugs other than fine them and either get them help or put them in jail.").

inappropriate prescriptions or otherwise diverted opioids, or specific pharmacy orders that were in fact suspicious. As explained in Part II, Plaintiffs presented ***no evidence***—from Rafalski or any other witness—that had Cardinal Health conducted more due diligence regarding any pharmacy order, it would have had reason to block or report as suspicious any more orders than it did.

Pre-2007. Rafalski's opinions that Cardinal Health failed to maintain effective controls to prevent diversion encompass the period from 1971 (when the DEA promulgated the anti-diversion regulations) to 2007. But, apart from the rote, conclusory opinions rendered at the close of his direct examination, Rafalski did not testify that Cardinal Health's pre-2007 system failed to comply with the regulations or that Cardinal Health's conduct in monitoring pharmacy orders was unreasonable. He described an Ingredient Limit Report, one component of the system, at some length,[26] but he did not criticize it.

To the contrary, his testimony established that Cardinal Health acted reasonably and in compliance with industry custom and practice. It established limits for each pharmacy customer—limits that Rafalski did not second-guess—and reported to the DEA any orders in excess of the limits—the same procedure that "***all companies***" ***followed for more than 30 years***.[27] Like all other distributors, Cardinal Health shipped the orders, but Rafalski admitted that "[t]he actual words 'do not ship' do not appear anywhere in the statute or regulations" and that before 2007 DEA "never specifically told McKesson, ABDC or Cardinal not to ship an

[26] Tr. (May 26) at 61–73.

[27] *Id*. at 61 ("all companies did it on a monthly basis and some companies did it on a daily basis"); *id*. at 269 (stating that he was not aware of any distributor that, before 2006, blocked every order it reported to the DEA).

order identified as suspicious."[28] More than that, Rafalski admitted that, as the chief investigator in *United States v. $463,497.72*,[29] he sat in courtroom when his colleague, agent Kyle Wright, testified that (i) DEA was aware that it was "standard practice" for distributors to ship orders that were reported as suspicious and (ii) DEA approved the practice.[30] It was in 2006 or 2007 that for "the first time the DEA made a more definitive statement 'do not ship.'"[31]

In sum, the evidence is uncontradicted that, for more than 30 years, Cardinal Health reported suspicious orders in the same manner as other distributors, and did so with the knowledge and tacit approval of the DEA. That is the very definition of reasonable conduct.[32]

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[28] *Id*. at 255; *id*. at 251 ("I do not know of that;" "no, I am not aware that they've said that in that way").

[29] 853 F.Supp.2d 675 (E.D. Mich. 2012).

[30] Tr. (May 26) at 259 ("Q. And as the chief investigator on this case, you never stood up to disagree with him, correct? A. I did not."); Dep. Tr. (Prevoznik) at 127 ("Q. And the DEA was aware that there were, in fact, being routinely submitted by distributors excessive purchase reports on a regular basis, right? A. We were aware.").

[31] Tr. (May 26) (Rafalski) at 254; *see Masters Pharmaceutical, Inc. v. D.E.A.*, 861 F.3d 206, 221–22 (D.C. Cir. 2017) ("[T]he Shipping Requirement mandates that pharmaceutical companies exercise 'due diligence' before shipping any suspicious order. … DEA first articulated that requirement in *Southwood* …."); Tr. (May 26) (Rafalski) at 268 (stating that the *Southwood* decision was in 2007). Not until 2009 did the DEA revise its internal manual to provide that a registrant should block a suspicious order and report it to the local DEA office. Tr. (June 9) (Rannazzisi) at 33 ("That's new to the manual.").

[32] Cardinal Health was not merely complying with industry custom and practice, which is presumptively reasonable. *Doe v. American National Red Cross*, 848 F. Supp. 1228, 1233-34 (S.D.W.V. 1994) ("[T]here is a presumption that adherence to the applicable standard of care adopted by a profession constitutes due care for those practicing the profession.") (quoting and adopting *United Blood Services v. Quintana*, 827 P.2d 509, 521 (Colo. 1992)); *Sexton v. Bell Helmets, Inc.*, 926 F.2d 331, 336 (4th Cir. 1991) ("While conformity with industry practice is not conclusive … the cases where a member of an industry will be held liable for failing to do what no one in his position has ever done before will be infrequent."); *Tri-State Roofing & Sheet Metal, Inc.*, 685 F.2d 878, 880 n.1 (4th Cir. 1982) ("[I]n most situations, the reference to industry custom and practice will establish the standard of conduct …."). It was complying with industry custom and practice, as approved by the DEA.

Post-2007. When the DEA made that "more definitive statement 'do not ship'" (in letters to distributors from Rannazzisi), the evidence is that Cardinal Health: (1) hired a well-qualified pharmacist and lawyer, Michael Mone, to lead and enhance its anti-diversion program;[33] (2) modified its policies and practices in accordance with the agency's new directive and its approval of the AmerisourceBergen system;[34] (3) made a week-long presentation about its modified and improved suspicious-order monitoring system to Barbara Boockholdt, Chief of the Regulatory Section of DEA's Office of Diversion Control, and several DEA diversion investigators;[35] (4) opened the doors of a number of Cardinal Health distribution centers to DEA inspectors, who did "a deep dive into the SOM system" for the purpose of verifying that it worked as presented to Ms. Boockholdt;[36] and (5) was otherwise "transparent with the DEA about the way Cardinal's SOM system worked."[37] The DEA at the time did not criticize the modified system for monitoring suspicious orders,[38] and Rafalski did not do so in his testimony. Asked by the Court whether procedures for blocking and reporting suspicious orders were "built

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33 Tr. (May 20) (Mone) at 152–54.

34 *Id.* at 157–58, 173–74.

35 *Id.* 219–20.

36 *Id*. at 223–24. For purposes of this "deep dive," the DEA requested information about particular customers and reviewed the due diligence files. *Id*. at 224.

37 *Id.* at 221.

38 *Id.* at 221, 223–24. In its regular inspections, the DEA would tell the registrant whether the suspicious-order monitoring system appeared to be working as it should, although the agency would stop short of formally approving the system. Tr. (June 8) (Rannazzisi) at 182 ("[b]ased on the policies and procedures that [DEA is] looking at, they would say it looks like it's operating appropriately").

into the system that all three of these defendants had in place" after 2007, Rafalski answered, "Yes, sir. Starting between 2007 and 2008, they all designed a system to do exactly that."[39]

The evidence is clear that the DEA did not require all distributors to implement a single, cookie-cutter system (although it did approve the AmerisourceBergen system and make a point of co-presenting it at a September 2007 briefing for distributors).[40] Rannazzisi testified that it was up to each distributor to "create their own system" and "to determine what's suspicious or what's not."[41] Rafalski did not disagree; indeed, he presented six different methods for monitoring suspicious orders and suggested that there might be even more that would comply with the anti-diversion regulations.[42] He testified about how Defendants set thresholds using averages and multipliers, but he did not criticize how Cardinal Health used averages to set thresholds or how it applied a multiplier to the averages.[43] Nor did he criticize any other of the policies and procedures that comprised Cardinal Health's post-2007 suspicious-order monitoring system,[44] nor the application of those policies to any Cabell/Huntington pharmacy,

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[39] Tr. (May 26) at 80. Rafalski did not testify that Cardinal Health moved too slowly in implementing these changes.

[40] Tr. (May 20) at 157.

[41] Tr. (June 9) at 170–71.

[42] Tr. (May 26) at 83–84.

[43] *Id*. at 68–74.

[44] *Id*. at 82 (there is no "one particular golden rule on what the trigger [i.e., threshold] should be"); 92 (regarding averages, "[i]t depends how … they set it, how the company sets it. They could set it by groups of pharmacies, individual pharmacies").

Michael Mone, who took charge of Cardinal Health's anti-diversion program in 2007, testified at length about the changes he made to those policies and procedures in order to bring the program in conformity with the AmerisourceBergen system, which he understood had been approved by the DEA, and which the agency co-presented to distributors as a model. Tr. (May 20) at 157–58, 173–74, 220–21; *see* Trial Ex. CAH-WV-00001 (SOP for a new retail independent customer survey process; Trial Ex. CAH-WV-00030 (SOP for the new account approval process); Trial Ex. CAH-WV-00745 (SOP to establish SOM threshold

What he criticized—and the sole basis for his opinion that Cardinal Health failed to maintain an effective anti-diversion control system—was the company's alleged failure to conduct adequate due diligence regarding flagged orders. Asked on direct examination whether he had been "asked [] to review all of the due diligence files," Rafalski answered that he had. And asked whether he had "gone through the customer files," he also answered that he had, and on that basis testified that he had not found "sufficient evidence … to dispel the suspicion of any of these orders … that were or should have been flagged."[45] But, on cross-examination, Rafalski backtracked. It turned out that he had reviewed only "some of the files"—definitely not the due diligence files for all the orders flagged by his methodologies, and not even "those initial orders for McKesson, Cardinal and ABDC that are the initial flagged orders under your Method A" (i.e., the initial flagged orders that topple the dominoes of all subsequent orders).[46] Asked whether he knew how many of the initial flagged orders, between 0 and 100 percent, "were actually investigated and the flag cleared by the defendants," Rafalski answered that he did not have a definitive answer.[47] And why not? Because "[t]hat's not something [he] tried to evaluate."[48]

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limits); Trial Ex. CAH-WV-00743 (SOP for threshold event review, self-verification; decision making and threshold outcome communication); Trial Ex. CAH-WV-00740 (updated SOP for detecting and reporting suspicious orders and responding to threshold events); Trial Ex. CAH-WV-00026 (SOP for on-site investigations); Trial Ex. CAH-WV-00747 (updated SOP for on-site investigations). As to the threshold-setting methodology, Mone testified it was submitted to multiple third party experts that validated the methodology, Tr. (May 20) 139, 142–43, and that Cardinal's threshold-setting policy was specifically shared with the DEA, Tr. (May 20) at 220–21.

45 *Id*. at 102.

46 *Id*. at 227–28 ("I have not, Your Honor.").

47 *Id*. at 228–29.

48 *Id*. at 229.

Rafalski guessed that Cardinal Health did not investigate orders flagged as suspicious ("I guess I couldn't rule out [the] possibility that one of them or two of them were investigated")[49] because he did not find documentation of the investigation and because the number of suspicious-order reports was not large. But, based on the evidence adduced in Plaintiffs' case, the absence of documentation (to the extent there was an absence) cannot reasonably support the inference that Cardinal Health did not investigate flagged orders.[50] The DEA imposes document retention requirements for certain documents, but ***not*** for due diligence files, as Rafalski acknowledged.[51] Cardinal Health produced transactional records for a much longer period than AmerisourceBergen or McKesson (from 1996),[52] which means that, in the absence of any legal requirement to do so, Cardinal Health would had to have retained due diligence files for 25 years for Rafalski to have found files from 1996, and for as long as 11 years for him to have found files for 2010.[53] Not only is Rafalski's inference from files he did not find unreasonable, but it

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[49] *Id*. at 228.

[50] It is important to note that the due diligence (or "investigation") Rafalski calls for does not entail "boots on the ground." "It's an internal investigation," he testified, "where they look at some internal information and facts and circumstances …." Tr. (May 26) at 76; Tr. (June 9) (Rannazzisi) at 98 ("we've never asked a distributor to do that [i.e., make "the determination if a controlled substance is medically necessary for a particular patient]").

[51] Tr. (May 26) at 269–70 ("Q. There's not a specific record retention requirement under law for federal due diligence files, correct? A. [I]n the Federal Register, it doesn't specifically speak to due diligence files."). For a number of these years, the documentation was "a paper system," and the Cardinal Health "records retention policy was two years." Tr. (May 20) (Mone) at 92–93.

[52] Tr. (May 26) (Farrell) at 104 ("This is Cardinal Health. Of the 92,915 transactions, which admittedly go into a longer data time frame than the other defendants …").

[53] Plaintiffs served document requests for the due diligence files in October 2019.

is contradicted by Mone's unqualified testimony that his anti-diversion team ***did*** investigate every order that exceeded the pharmacy's threshold.[54]

Rafalski insinuated that the number of orders reported to the DEA was small, given the number of orders flagged by his methodologies.[55] But if, as Mone testified, Cardinal Health did conduct internal due diligence for orders that exceeded the thresholds—and satisfied itself that the orders were appropriate—the numbers it reported to the DEA were in line with what a properly functioning suspicious-order monitoring system would generate. As Rannazzisi explained in answer to the Court's question:

> [***U***]***nderstand the volume of suspicious orders that should come in is not a huge quantity of orders. It shouldn't be like boxes of orders***. It should be a very specific order that outlines why it's suspicious, what triggered the suspicion, what triggered the order, what's the historical ordering pattern. And then we would follow up. But, but we're not talking about 100, 1,000 orders. We're talking about specific suspicious orders.[56]

Rafalski's testimony makes it clear that he had no factual basis for rendering an opinion that the number of reported orders is low, high, or just right. He did not know how many Cabell/Huntington doctors prescribed opioids for a legitimate versus illegitimate purpose:

> Q. [Y]ou conducted no analysis of how many doctors were prescribing legitimately in Huntington/Cabell versus illegitimately. True?

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[54] Tr. (May 20) at 62 ("[E]very order that triggers is going to have some sort of due diligence."). As noted before, Rafalski did not fault how Cardinal Health set thresholds or the threshold set for any particular pharmacy in Cabell/Huntington.

[55] Tr. (May 26) at 104–05 (providing the number of suspicious-order reports by year). Notably, Rafalski did not testify that these numbers were too low.

[56] Tr. (June 7) at 219–20.

> A. ***I did not conduct any research on that and I did not look into that matter***. So I do not have an opinion on that.[57]

He did not know how many pills distributed by Cardinal Health were dispensed other than to fill a prescription written by a licensed doctor:

> Q. [A]re you aware of any pills that were shipped by McKesson, ABDC, or Cardinal that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription?
>
> A. No, I'm not, Your Honor.[58]

And he was unable to name any pharmacy customer of Cardinal Health that filled prescriptions written by a pill-mill doctor or otherwise failed to comply with its legal obligations[59]—and so had no opinions "about whether diversion occurred at a pharmacy level."[60]

In sum, for the post-2007 period, Rafalski's opinion that Cardinal Health did not maintain an adequate anti-diversion system, and therefore acted unreasonably, rests on his review of only "some" of the due diligence files produced in the litigation and the unsupported inference that the absence of old files that Cardinal Health had no legal obligation to retain meant that the

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[57] Tr. (May 26) at 127–28, 216, 218. Plaintiffs' expert, Dr. Keller, also had no opinion whether any Cabell/Huntington doctor, including those who wrote the largest number of opioid prescriptions, did so other than for a legitimate medical purpose. Tr. (June 15) at 116, 165. She did identify one doctor (Deleno Webb) who wrote a large number of opioid prescriptions, some of which were filled by Cardinal Health customers (Medicine Shoppe, for four months, as far as the record evidence indicates) and Drug Emporium Barboursville (an AmerisourceBergen customer for more than ten years; a Cardinal Health customer only since 2015). *Id*. at 188; 130. The opioid prescriptions by Dr. Webb, however, constituted just 0.2 percent of the prescriptions dispensed by the Drug Emporium.

[58] Tr. (May 26) at 131.

[59] Tr. (May 26) at 134.

[60] *Id*. at 135. Speaking for the DEA, Rannazzisi testified that "we don't investigate [doctors] based on quantities," Tr. (June 9) at 112, and Dr. Gupta, speaking for the Board of Medicine, testified that it would not initiate an investigation based on the fact that a doctor prescribed a large volume of opioids, even was among the top five prescribers of opioids in the State. Tr. (May 6) at 143.

company did not do due diligence. This testimony, taken alone, lacks credibility and heft. Viewed alongside (1) the testimony of Mone, who explained (i) how he modified the Cardinal Health system to incorporate the three major components of the AmerisourceBergen system that had been approved and co-presented by the DEA to all distributors and (ii) how he himself presented the system to the Chief of the Regulatory Section, DEA Office of Diversion Control, receiving tacit approval, (2) Plaintiffs decision not to offer any evidence about the post-2012 period,[61] Rafalski's testimony deserves no weight.

B. Mone's Testimony Established that Cardinal Health Designed and Operated a Reasonable System for Monitoring Pharmacy Orders.

In 2006-2007, when the DEA reinterpreted the anti-diversion regulations and communicated its new expectations to distributors through a series of letters and briefings, Cardinal Health responded promptly and comprehensively. First, the company installed new leadership. In December 2007, Cardinal Health hired Michael Mone to direct and enhance the anti-diversion program. As a pharmacist and lawyer, Mone had both a range and depth of experience, working as (i) a practicing pharmacist, (ii) prosecutor for the Florida Board of Pharmacy, (iii) attorney in the Florida Attorney General's Office dealing specifically with opioid issues, and (iv) Executive Director of the Kentucky Board of Pharmacy, where he created one of the nation's first Prescription Drug Monitoring Programs.[62]

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[61] If Plaintiffs contend that the post-2012 system was unreasonable in any way, it was their burden to adduce evidence about the system and show that it was unreasonable. They did not do that. Todd Cameron followed Mone as the head of Cardinal Health's anti-diversion program in 2012. Counsel agreed upon a date for his appearance in Plaintiffs' case, and Cameron traveled to Charleston to testify, only to have Plaintiffs drop him as a witness. For that reason, unlike for AmerisourceBergen and McKesson, there is little, if any, evidence about Cardinal Health's further enhanced system, post-2012.

[62] Tr. (May 20) at 152–54.

Second, Mone oversaw the incorporation into Cardinal Health's system of the three main components of the DEA-approved AmerisourceBergen system: (1) "Know Your Customer," (2) electronic order monitoring, and (3) investigations.[63] The "Know Your Customer" component involved changes to evaluate new customers more thoroughly (i.e., by using detailed questionnaires) and enhance diligence regarding existing customers.[64] The changes meant that approval of new customers was not automatic: Mone testified that Cardinal Health refused to approve certain prospective customers due to diversion concerns.[65]

Cardinal Health also introduced electronic order monitoring and established customized thresholds for each customer and each family of drugs.[66] In building its updated system, the company consulted with experts at Deloitte, IBM Watson, and Ohio State, who validated the analytical approaches for evaluating customers and monitoring orders.[67] The enhanced system enabled the company automatically to block any order that exceeded the threshold pending evaluation by the anti-diversion team, which was comprised of in-house pharmacists.[68] The

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63 *Id.* at 158, 173–74.

64 *Id.* at 173–74.

65 *Id.* at 221–22. The "Know Your Customer" process was somewhat different for chain pharmacy stores, as authorized by the DEA at the September 2007 AmerisourceBergen/DEA conference. *See* Trial Ex. DEF-WV-0001 (PowerPoint re: AmerisourceBergen SOM System from September 2007 DEA conference) at .00007 ("[r]etail chain pharmacies are exempted" from "'Know Your Customer' Due Diligence investigations"); Trial Ex. DEF-WV-02191 (DEA website summary of September 2007 conference) at .00002 (same). In any event, there is no evidence that Cardinal Health approved a chain-pharmacy store it should not have.

66 Tr. (May 20) at 143.

67 *Id.* at 143. Cardinal Health also relied in part on the DEA's Chemical Handlers Manual, which provided a framework for identifying excessive orders of List I chemicals, which include certain controlled substances. *Id.* at 93–94.

68 *Id.* at 185–87.

revised policies provided that, if the anti-diversion team determined that an order was in fact suspicious, Cardinal Health reported the order to the DEA and did not ship it.[69]

Regarding the investigations component of the revised system, Cardinal Health hired new staff (former police and former DEA-diversion, Medicaid-fraud, and Board of Pharmacy investigators) to conduct site visits.[70] It created and staffed an analytics team to support the monitoring system in establishing carefully calibrated thresholds and running reports.[71] And, under Mone's direction, it adopted comprehensive Standard Operating Procedures ("SOPs") periodically updated those procedures, and trained and tested "just about everybody."[72]

As noted above, Mone made a full presentation of Cardinal Health's updated system to the DEA, which met with him at the company's headquarters for a week, requested and reviewed due diligence files for certain customers, and subsequently conducted inspections of a number of Distribution Centers to observe the system in operation.[73] In addition, throughout the post-2007 period, the DEA continued to carry out its unannounced, cyclical inspections of Cardinal Health facilities.[74] At no point did the DEA fault the changes put in place under Mone's direction. The

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69 *Id.* at 189.

70 *Id.* at 174, 187–88.

71 *Id.* 83, 174, 199.

72 Tr. (May 20) at 192 ("the sales folks, the sales op folks, my folks, and the distribution center employees"); *see, e.g.*, Trial Ex. CAH-WV-00001 (SOP for a new retail independent customer survey process; Trial Ex. CAH-WV-00030 (SOP for the new account approval process); Trial Ex. CAH-WV-00745 (SOP to establish SOM threshold limits); Trial Ex. CAH-WV-00743 (SOP for threshold event review, self-verification; decision making and threshold outcome communication); Trial Ex. CAH-WV-00740 (updated SOP for detecting and reporting suspicious orders and responding to threshold events); Trial Ex. CAH-WV-00026 (SOP for on-site investigations); Trial Ex. CAH-WV-00747 (updated SOP for on-site investigations).

73 Tr. (May 20) at 219–21, 222–24.

74 *Id.* at 225.

enforcement actions settled in 2008 and 2012 did not involve systemic failures, but issues at a small number of Distribution Centers. The first settlement concerned shipments from distribution centers in Auburn, Washington; Lakeland, Florida; Swedesboro, New Jersey, and Stafford, Texas,[75] while the later settlement concerned only the Lakeland center and four Florida customers (two of which Cardinal Health had terminated before the DEA filed the enforcement action).[76]

Cardinal Health at all times distributed prescription opioids to Cabell/Huntington pharmacies from its Wheeling, West Virginia Distribution Center, which has been licensed by the Board of Pharmacy and registered with the DEA at all times.[77] Both the Board and the DEA have regularly inspected the facility. Of particular relevance, therefore, is the fact that the Board and the DEA, in their inspection write-ups, never faulted its anti-diversion procedures or practices.[78] And neither the 2008 nor 2012 settlements between Cardinal Health and the DEA concerned activities at the Wheeling Distribution Center. There is no evidence that the Center shipped prescription opioids to a pharmacy that it knew or had reason to believe was ordering opioids other than to fill legitimate prescriptions.[79]

* * *

[75] *Id.* 165–66.

[76] *Id.* at 228–30. While Rannazzisi testified that the alleged failures that were the basis for these settlements were "systemic," his testimony made clear that he considered any failure, no matter how limited in time or location, to be systemic. Tr. (June 8) at 64, 90.

[77] Tr. (May 20) at 193–94.

[78] *Id.*

[79] *Id.* at 180.

In briefing, Plaintiffs have taken the position that "in West Virginia, the touchstone of public nuisance liability is unreasonableness."[80] That unreasonableness standard applies to Cardinal Health's ***conduct***. Plaintiffs did not prove that Cardinal Health acted unreasonably. For more than 30 years, like every other wholesale distributor, it reported suspicious orders in a manner known to, and approved by, the DEA, as the district court found in *United States v. $463,497.72*. Then, when the DEA changed its interpretation of what the regulations required and showcased a suspicious-order monitoring system developed in partnership with AmerisourceBergen, Cardinal Health hired new leadership to implement the components of that system, made a full presentation of the system to the DEA, and opened its due diligence files at headquarters and Distribution Centers to inspection by the agency. Even more fundamentally, Cardinal Health acted reasonably because—like the DEA itself, which raised the annual quota for opioids every year for 15 years and pronounced that 99.5 percent of doctors were prescribing opioids for a legitimate medical purpose—the company understood that the rise in prescribing reflected a new standard of care for prescribing opioids—one that had the blessing of national medical societies, the Federation of State Medical Boards, the West Virginia Board of Medicine, the Joint Commission on Accreditation of Healthcare Organizations, and payors.

Because they cannot prove that Cardinal Health acted unreasonably, Plaintiffs ask this Court to find the company liable regardless of the reasonableness of its conduct. The formula they ask the Court to apply is High Volume of Pills + High Level of Addiction/Overdoses = Liability.[81] That is a request for the Court to hold Cardinal Health strictly liable for shipping

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[80] Plaintiffs' Mem. in Opp. to Joint Motion for Summary Judgment For Failure to Prove Fault Element of Public Nuisance Claims, Dkt. 1075 at 8.

[81] *See* Tr. (July 1) at 105 ("What we would say is the measurement of whether or not their conduct was reasonable can be determined by looking at the volume of pills they sold either on a local level, regional level, state level, or national level.").

prescription opioids to DEA-registered and state-licensed pharmacies in order to fill prescriptions written by DEA-registered and state-licensed doctors, 99.5 percent of whom were prescribing appropriately, according to the regulators whose job it was to know. That request reflects a fundamental failure of proof and should be denied.[82]

II. PLAINTIFFS FAILED TO PROVE THAT ANY UNREASONABLE CONDUCT CAUSED THEM HARM[83]

Proof of causation in this case, as in all cases, has two aspects: Plaintiffs were required to prove (1) cause-in-fact (i.e., that but for Cardinal Health's unreasonable conduct, the harm would not have occurred) and (2) proximate causation. Plaintiffs presented ***no evidence*** that Cardinal Health's conduct was a cause-in-fact of the opioid epidemic or, in turn, Plaintiffs' harm. And what evidence Plaintiffs did present regarding causation failed to establish that Cardinal Health's conduct was a proximate, or direct, cause of Plaintiffs' harm.

A. No Evidence of Cause-in-Fact

Plaintiffs contend that Cardinal Health shipped pharmacy orders for opioids that it should have (i) flagged as suspicious, (ii) investigated to determine if the orders were in fact suspicious, and, if investigation did not clear suspicion, (iii) reported to the DEA as suspicious and not shipped. To prove cause-in-fact, Plaintiffs therefore were obligated to establish:

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[82] Cardinal Health hereby adopts Part II of ABDC's Rule 52(c) motion, Dkt. 1443.1, which sets forth the reasons why Plaintiffs cannot prove actionable conduct against Defendants based on alleged violations of the federal or West Virginia Controlled Substances Acts.

[83] Plaintiffs have failed to prove fault, as explained in Part I, *supra*. For purposes of this section, we assume for purposes of argument that Plaintiffs did prove fault and show that, even so, Cardinal Health is entitled to judgment because Plaintiffs presented (i) no evidence of "conduct causation" or "harm causation" and (ii) inadequate evidence of direct causation.

- that had Cardinal Health ***conducted adequate due diligence*** regarding the orders Plaintiffs deem "suspicious," Defendants would have had reason to block some significant number of those orders;[84]

- that had Cardinal Health ***blocked*** a significant number of orders, or even terminated one or more pharmacy customers, there would have been a commensurate diminution of shipments of prescription opioids to Cabell/Huntington; ***and***

- that had Cardinal Health ***reported to the DEA*** the orders Plaintiffs deem "suspicious," the DEA would have taken enforcement action against doctors and/or pharmacies—action that, in turn, would have stopped (or substantially curtailed) the prescribing and consequent dispensing of opioids.

That is, would doing suspicious order monitoring "the right way" (according to Plaintiffs) have produced a different outcome? Would it have resulted in (i) blocking more pharmacy orders (because of better due diligence), (ii) reducing the supply of pills (because pharmacies could not fill their orders with another distributor), or (iii) greater DEA enforcement activity (because of reporting more suspicious orders)? Plaintiffs presented ***no evidence*** that it would have, and that failure alone warrants judgment for Defendants.

Plaintiffs presented no witness that even addressed that question. Plaintiffs' liability expert, James Rafalski, testified in general terms that each Defendant's suspicious order monitoring system was inadequate. And he devised methodologies (applied by Dr. McCann) that identified more than 90 percent of pharmacy orders as suspicious and as therefore calling for

[84] The DEA regulations are plain on their face that they do not impose a no-ship requirement, and the evidence has established that the agency so interpreted the regulations for more than 30 years after their enactment in 1971. Then, between 2005 and 2007, without notice-and-comment rulemaking or the issuance of any formal guidance, the DEA purported to re-interpret the regulations. *See* pp. 11–12 & n. 31, *supra*. For present purposes, however, we assume that Cardinal Health had a duty to report suspicious orders before 2007 and a duty to block shipment of suspicious orders after 2007.

due diligence before they could be shipped. But Rafalski stopped there—and so stopped short of addressing "but for" causation.[85]

Cause-in-fact re due diligence. ***No witness*** testified that additional due diligence by Cardinal Health would have caused it to block shipment of more pharmacy orders than it did already. To begin with, ***no witness*** testified (i) for any particular pharmacy customer of Cardinal Health and (ii) for any specific pharmacy order (iii) regarding what due diligence should have been done that was not done. Nor did any witness testify as to what "appropriate" due diligence required. Rafalski simply assumed across the board—without considering what any Defendant did with respect to any specific order—that Defendants did no (or inadequate) due diligence.[86] The more fatal omission, however, is that he did ***nothing*** to evaluate whether "adequate" due diligence would have determined that any material number of the orders flagged as suspicious by his methodologies were, in fact, suggestive of diversion and therefore should have been blocked.

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[85] For the reasons given in Defendants' renewed *Daubert* motion on Rafalski (Dkts. 1385, 1386, 1398, 1405, and 1408), the Court should exclude Rafalski's testimony. For purposes of this argument regarding causation, we assume that Rafalski's testimony and the flagging methodologies are admissible. Rafalski did offer an opinion regarding proximate causation, although the Court twice sustained an objection to it. *See* n. 134, *infra*.

[86] Tr. (May 26) at 227 (Method A "*assum*[*es*] that distributors did not conduct any diligence on the first flagged suspicious order"). While Rafalski initially testified that he had gone through the customer files produced by Cardinal Health and not found "sufficient evidence" to "dispel the suspicion" supposedly attached to the orders flagged by his Method A, *id*. at 102, he acknowledged on cross-examination that he did not review the due diligence files for all the orders flagged by Method A—only "some." *Id.* at 228. And he admitted that he has no idea how many of those flagged orders Cardinal Health in fact investigated and cleared of suspicion. *Id.* at 228–29.

The evidence reflects that Cardinal Health did in fact evaluate suspicious orders. *See*, *e.g*., Tr. (May 20) (Mone) at 62 ("[E]very order that triggers is going to have some sort of due diligence."). For purposes of this argument, however, it does not matter whether Cardinal Health performed adequate due diligence or not.

In other words, he did not address whether, ***but for*** Cardinal Health's alleged failure adequately to evaluate suspicious orders, it would have blocked any more orders than it did.

Whatever "adequate" due diligence requires, no one contends that a wholesale distributor's obligation extends to investigating doctors' prescribing decisions, as both Rafalski and Rannazzisi admitted.[87] Rannazzisi was unequivocal on this point:

> Q. [***Distributors***] ***don't evaluate a patient's legitimate medical need for opioids in terms of deciding whether the opioids are appropriate for that patient***, correct?
>
> A. ***That's correct***.
>
> Q. They can't second-guess legitimate medical decisions by prescribers, correct?
>
> A. I don't understand when they would be questioning a legitimate medical prescription.
>
> Q. And they don't have access to individual medical records because of privacy laws, correct?
>
> A. They wouldn't have access to that.
>
> Q. There's been discussion in this case about a term "know your customer's customer." That's not a term you were familiar with during your time with DEA, correct?
>
> A. ***No***. "Know Your Customer," ***not*** "Know Your Customer's Customer."[88]

Rafalski agreed:

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[87] Tr. (May 26) (Rafalski) at 117 ("Q. The DEA does not expect distributors to second-guess the legitimate medical judgments of prescribers. True? A. Well, I would agree with that … in general terms unless they were to know some information or observe something way outside of the normal."); Tr. (June 9) (Rannazzisi) at 98 ("Q. And a distributor cannot make a determination if a controlled substance is medically necessary for a particular patient, correct? A. Yes. And we've never asked a distributor to do that.").

[88] *Id.* at 154–55.

> Q. There's … ***no requirement*** in the regulations that distributors have to affirmatively determine that prescribing decisions are legitimate, is there?
>
> A. I'd agree with that.[89]

Even had Defendants conducted such a level of due diligence, the evidence in the record establishes that such due diligence, prompted by pharmacy orders for an increasing volume of opioid medications, would likely have determined that the orders reflected an increased number of prescriptions (often for more pills or stronger doses) that, in turn, reflected a more permissive standard of care for treating chronic pain with opioids. Rafalski admitted on cross-examination that the "overwhelming majority" of doctors prescribed opioids for legitimate medical purposes and that their prescribing did not warrant regulatory scrutiny:

> Q. [I]t says in 2006 in the Federal Register in this official DEA policy statement, DEA recognizes that the overwhelming majority of American physicians who prescribe controlled substances do so for legitimate medical purposes. Do you disagree with that statement?
>
> A. I do not.
>
> Q. You agree with that?
>
> A. Yes, Your Honor, I agree with that.
>
> Q. In fact, ***the overwhelming majority of physicians who prescribe controlled substances do so in a legitimate manner that will never warrant scrutiny by federal or state law enforcement officials. Do you agree with that***?
>
> A. Your Honor, ***I do agree with that statement***, too.[90]

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[89] Tr. (May 26) at 117.

[90] Tr. (May 26) at 120–21. He further agreed that 99% of doctors prescribe opioids for legitimate medical purposes. *Id*. at 121–22; *see* Tr. (June 9) (Rannazzisi) at 101 ("99 percent of doctors were perfect.").

If so, then no amount of due diligence by Cardinal Health (or the other Defendants)—not even being a fly on the wall of doctors' offices or standing behind pharmacy counters, both of which distributors are legally prohibited from doing—would have given it reason to report or block the overwhelming majority of pharmacy orders.

The testimony of other witnesses also established that due diligence would only have confirmed that the increased volume of pharmacy orders reflected a change in the prevailing medical guidelines for prescribing opioids. Plaintiffs' first witness, Dr. Corey Waller, testified that the standard of care for prescribing opioids changed, becoming more permissive, in the 1990s. Like doctors in West Virginia, each of whom received a copy of *Responsible Opioid Prescribing* from the West Virginia Board of Medicine, he received the same book from the Michigan Board of Medicine upon completing his residency. In 2018, he co-edited the *American Society of Addiction Medicine Handbook on Pain and Addiction*, which, in the chapter entitled "Understanding and Preventing Opioid Misuse and Abuse," cited *Responsible Opioid Prescribing* as a resource for further information. Notably, it is *Responsible Opioid Prescribing*, published by the Federation of State Medical Boards, that Plaintiffs allege (in retrospect) was a cause of the problem—because the book "advanced the concept of pseudo-addiction" and "asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins; that pain is under-treated; and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient."[91] According to Plaintiffs, the guidelines promulgated by *Responsible Opioid Prescribing* and sponsored by the West Virginia Board of Medicine (and others) caused "widespread prescribing of opioids for common, chronic pain conditions like low

[91] TAC ¶¶ 443, 569.

back pain, arthritis, and headaches."[92] Such prescribing, Dr. Waller testified, "was the ***general gestalt*** at the time given that pain as the fifth vital sign was being implemented in hospitals and as such that it was felt that that was the only lever we had to pull for the treatment of pain …"[93] And doctors who prescribed in accordance with "the general gestalt," he said, "were acting in good faith."[94]

Dr. Rahul Gupta, the former West Virginia Commissioner of Public Health, agreed that most doctors thought they were doing the right thing: "[t]heir intent was to help their patient because ***that was the culture. That was the education. That was the influence. That was their understanding***."[95] The prevailing "culture" of prescribing was one "of attempting to reduce pain from a scale of whatever to zero for … every West Virginian that they could possibly do."[96] Dr. Werthammer ruefully admitted the same fact, acknowledging his 2016 email to a medical colleague, "Unfortunately, it was not big pharma who wrote the prescriptions. It was me and my colleagues, Joe."[97] And Dr. Keyes acknowledged that "the opioid crisis would not have occurred if prescribing opioids had not become ***standard practice*** in managing acute and chronic pain."[98]

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92 *Id*. at ¶ 315; Tr. (May 4) at 118 ("Q. Now, that's the same book that plaintiffs allege here misled doctors about the risks of prescribing opioids and causing them to overprescribe opioids; correct? [Waller] That's correct.").

93 *Id.* at 103.

94 *Id.* at 104.

95 Tr. (May 6) at 94.

96 *Id*. at 90.

97 Tr. (May 21) at 31.

98 Tr. (June 14) at 82.

Most significantly, the trial record provides no basis to conclude that more due diligence would have given Cardinal Health reason to block more orders when, according to Rannazzisi, the former Deputy Assistant Administrator for the DEA's Office of Diversion Control: (1) 99.5 percent of doctors were "perfect" in their prescribing of opioids,[99] (2) less than 0.1 percent of doctors lose their controlled substance registrations in a given year,[100] (3) a high-volume of prescriptions by a doctor would not alone raise suspicions of improper prescribing,[101] (4) a pharmacy's filling of prescriptions written by a pain clinic would not be reason for the DEA to deny registration to that pharmacy,[102] and (5) the DEA never warned Cardinal Health (or any Defendant) not to supply a pharmacy in Cabell/Huntington because of a risk of diversion.[103]

Thus, the evidence adduced in Plaintiffs' case established that, ***even if*** Defendants' due diligence had extended to an examination of the reasons why Cabell/Huntington doctors prescribed opioids, the overwhelming likelihood is that that inquiry would have confirmed that the prescriptions conformed to the prevailing standard of care. For this reason, more or different due diligence would not have revealed "black flags" of diversion, but only that pharmacies were filling prescriptions written in good-faith by doctors following the then-prevailing standard of care for prescribing opioids. That standard of care (in retrospect) may have been too permissive and (according to Plaintiffs' allegations) was influenced by the Manufacturers' alleged deceptive marketing. But no amount of due diligence at the time would have resulted in blocking

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[99] Tr. (June 9) at 101–02.

[100] *Id*. at 109.

[101] *Id*. at 112–13 ("So we don't investigate based on quantities.").

[102] *Id*. at 136.

[103] *Id*. at 151–52.

pharmacy orders that were based on good faith prescribing pursuant to the prevailing standard of care.[104]

Cause-in-fact re shipments. Even had Cardinal Health blocked more suspicious orders or even terminated the pharmacy customers that placed the orders, there is no evidence that the supply of prescription opioids to Cabell/Huntington would have changed. Approximately 36 distributors supplied Cabell/Huntington pharmacies,[105] and one aspect of distributor-representative's job was, where possible, to poach another distributor's customer.[106] Rafalski acknowledged the obvious: that "when a distributor cuts off a customer, it's common that that pharmacy will go find another distributor to supply its pills."[107] He was not aware of any instance where a pharmacy could not find another distributor.[108]

Cause-in-fact re reporting. Also, ***no witness*** testified that, but for Cardinal Health's alleged failure to flag, investigate, and report more orders as suspicious, the DEA would have cracked down on doctors that were prescribing, or pharmacies that were dispensing, too many opioids in a manner that would have reduced the amount of prescription opioids in Cabell/Huntington.

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[104] If Rafalski (or anyone) had evaluated the actual pharmacy orders that he opined should have been flagged as suspicious, it is always possible that he might have identified some order that was likely to be diverted. But *no one* did that evaluation.

[105] Tr. (May 11) (McCann) at 153–54.

[106] *See, e.g.*, Tr. (May 19) (Perry) at 198 ("You know, from time to time we would win a contract or lose a contract. So we may have the business for, you know, maybe five years, and then we would lose it to a competitor. And then when that contract would be up, we would bid for that contract again and we may win it back.").

[107] Tr. (May 26) at 149.

[108] *Id*. at 149–50. The only way to stop a rogue doctor or pharmacy, Rafalski agreed, is for the DEA to withdraw their authorization to prescribe or dispense controlled substances or for the Boards of Medicine/Pharmacy to suspend their licenses. *Id.* at 150.

To the contrary, the evidence elicited in Plaintiffs' case demonstrated that DEA likely would not have taken such action. In their opening statement, Plaintiffs told the Court that their case would be based on "the volume of pills that were sold by The Big Three into Huntington-Cabell County."[109] "The first pillar" was volume, counsel said, and "[t]he volume comes from ARCOS."[110] But from the beginning, and at all times, the DEA knew the volume of pills being distributed to Cabell/Huntington because, month-by-month, Defendants reported ***each and every*** shipment of prescription opioids to their Cabell/Huntington pharmacy customers.[111] Indeed, Plaintiffs' expert, Dr. McCann, confirmed the accuracy of the shipment/transaction data reported by each Defendant and relied on that data for his own analysis.[112] Thus, DEA knew the volume of pills distributed to each Cabell/Huntington pharmacy customer by each Defendant (and by every other wholesale distributor, of which there were more than 30)[113]—and knew, too, the ***total*** volume of pills distributed to each pharmacy and to the Cabell/Huntington area.[114]

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[109] Tr. (May 3, 2021) at 13.

[110] *Id*. at 23.

[111] Tr. (May 12) (McCann) at 64; Tr. (May 26) (Rafalski) at 202. Plaintiffs elicited testimony that this reporting of every shipment was not in "real time." Tr. (June 10) (Rannazzisi) at 25. But any "lag" due to monthly or quarterly reporting was not material. It did not prevent the DEA from observing on a monthly or quarterly basis, year and year, the volume of prescription opioids shipped to every pharmacy, city or county and taking action if it believed the volume was excessive.

The DEA did not tell Cardinal Health that the volume of shipments to Cabell/Huntington (or any particular pharmacy) was excessive. Tr. (May 26) (Rafalski) at 179 (the agency never "look[ed] at the overall distribution or any one distributor's distribution to Huntington or Cabell County and ma[de] a judgment that it should be different").

[112] Tr. (May 10) at 18–19.

[113] Tr. (May 12) at 24–25; Tr. (May 26) (Rafalski) at 150.

[114] Tr. (May 26) (Rafalski) at 173 (DEA knew the "volume of opioids supplied by all distributors to a pharmacy" and "to a county").

This, Plaintiffs' counsel said, is all one needed to know to identify Cardinal Health and the other Defendants as bad actors.[115] But the DEA knew this information,[116] and the evidence demonstrates that knowing it did not prompt the agency to take any enforcement activity—or any action whatsoever—to limit prescribing, dispensing, or distributing. As Plaintiffs' counsel told the Court in his opening statement, "not until recently were they [the DEA] using [the ARCOS data] on a pro-active basis to look for trends."[117] The DEA did not advise Defendants that the total volume of shipments to the area (or any particular pharmacy) was excessive[118]—in fact, never "look[ed] at the overall distribution or any one distributor's distribution to Huntington or Cabell County and ma[de] a judgment that it should be different."[119] Nor did the DEA question the prescribing by hundreds of Cabell/Huntington doctors that accounted for the volume of shipments.[120] Far from questioning the level of prescribing, the DEA told Congress that 99.5

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[115] Tr. (May 3) at 11 ("[T]he law of parsimony or Occam's philosophical razor suggests the simplest explanation is usually the right one …. We intend to prove the simple truth that the distributor defendants sold a mountain of opium pills into our community fueling the modern opioid epidemic.").

[116] So, too, did Plaintiffs and the Boards of Pharmacy and Medicine, because from 2003 forward the DEA posted the information on its website by three-digit zip code prefix.

[117] Tr. (May 3) at 24.

[118] Tr. (June 9) (Rannazzisi) at 92 ("Q. When you were at DEA, did you ever issue guidance to distributors, the healthcare community, doctors that these [hydrocodone] levels were too high? A. No, I did not."); *id.* at 94 ("Q. Did DEA ever issue any guidance … at any point in time to healthcare providers, manufacturers, distributors, pharmacies that specific levels at the zip code level were too high? A. No. DEA would not issue something like that.").

[119] Tr. (May 26) (Rafalski) at 179; *id*. at 173 (DEA knew the "volume of opioids supplied by all distributors to a pharmacy" and "to a county").

[120] Plaintiffs' expert, Dr. Keller, testified that from 1997 to 2010, there were between 350 and 600 doctors in Cabell/Huntington who prescribed opioids. Tr. (June 15) at 204. She identified no more than four doctors in the area who were disciplined by the Board of Medicine or Board of Osteopathic Medicine. *Id*. at at 136, 142, 182, 233.

percent of opioid prescribing was for a legitimate medical purpose[121]—indeed, according to Rannazzisi, "99 percent of doctors were perfect."[122] Of the one percent or less who were not "perfect," Rannazzisi could not say whether any of those doctors were in Cabell/Huntington.[123] And, as the prescribing of opioids increased, the DEA did not act to curb the number of West Virginia practitioners registered to prescribe opioids: to the contrary from 2005 to 2015, that number increased by more than one thousand.[124]

Rannazzisi testified on direct examination that the agency investigated suspicious order reports.[125] Not "every one," of course[126]—and far short of every one if, as the Inspector General reported in 2019, the DEA field office staff did not receive access to the Suspicious Order Reporting System until 2017, ten years after it was created.[127]

In any event, because Plaintiffs contend that it was the ***overall volume*** of prescription opioids distributed to Cabell/Huntington that both raised a "black" flag and heightened the risk of diversion, the reporting of suspicious orders was, in a sense, a redundant requirement. Suspicious order reporting focuses on a subset of the volume and may identify a possible bad

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[121] Tr. (June 9) at 99; *see* Tr. (June 8) (Rannazzisi) at 184 ("Q. … [W]ere most healthcare providers prescribing appropriately? A. Yes.").

[122] Tr. (June 9) at 101–02.

[123] *Id*. at 112.

[124] *Id*. at 162. The number of registered pharmacies by almost 100, a comparable increase of approximately 20 percent. *Id*.

[125] Tr. (June 8) at 112.

[126] *Id*.

[127] Tr. (June 9) (Rannazzisi) at 168–70 (not disputing the fact, but stating that one diversion manager so stated). Even if the Field Offices had had access to the System, the Inspector General reported that only eight of roughly 1400 registrants reported suspicious orders to the System. The rest sent reports to various Field Offices, where the Inspector General found "staff were unaware of the requirement to maintain the reports and could not locate them." Trial Ex. DEF-WV-01597 at 31.

actor pharmacy or physician. But Plaintiffs do not claim, and have not presented evidence, that any such bad actors substantially contributed to the opioid epidemic in Cabell/Huntington. Rannazzisi testified that the DEA would never initiate an investigation simply because a doctor was in the top one percent of prescribers (in terms of volume of opioids prescribed).[128] And Rafalski testified that he cannot "identify a single doctor … in Cabell County or Huntington who was prescribing improperly or engaging in diversion."[129]

Rannazzisi testified that, if there is proper suspicious-order reporting, "the volume of suspicious orders that should come in is not a huge quantity of orders. It shouldn't be like boxes of orders"[130]—a conclusion that follows naturally from his testimony that 99.5 percent of doctors prescribed opioids for a legitimate medical purpose. Cardinal Health and the other Defendants did report suspicious orders in the post-2007 period, but when asked whether he could identify a single one of those reports "that resulted in investigations," Rannazzisi answered, "I don't know."[131] And Rafalski, asked whether he could point to "any orders" shipped by Defendants to Cabell/Huntington where "the DEA came to them and said you should not have shipped that specific order," Rafalski answered, "That's a true statement. … I didn't—do not know that."[132]

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[128] Tr. (June 9) (Rannazzisi) at 112–13 ("So we don't investigate based on quantities.").

[129] Tr. (May 26) at 128; *id*. at 131 (unaware of any pills shipped by Defendants "that ended up filling a prescription that was dispensed other than in response to a licensed prescriber writing a prescription"). Plaintiffs' expert, Dr. Keller, identified a small number of Cabell/Huntington doctors who wrote a large number of opioid prescriptions. But, like Rafalski, she did not testify that these (or any) doctors improperly prescribed opioids or engaged in diversion. And she did not establish that the prescriptions written by any of these doctors constituted an appreciable percentage of the orders placed by a pharmacy that was a Cardinal Health customer. *See* n. 57, *supra*.

[130] Tr. (June 7) at 219.

[131] Tr. (June 9) at 167.

[132] Tr. (May 26) at 206.

That suspicious-order reporting did not lead to enforcement is not surprising, for Rannazzisi acknowledged that a 2019 report of the Office of Inspector General found that DEA Field Division Staff—the personnel who initiate investigations—did not receive access to the suspicious order reporting system until 2017.[133]

Accordingly, there is no basis in the record to conclude that, had Cardinal Health reported more orders as suspicious, the DEA would have taken any action—much less successful enforcement action that would have had a material effect on the level of opioid prescribing or dispensing for Cabell/Huntington residents. Absent such evidence, Plaintiffs failed to prove cause-in-fact.

* * *

Accordingly, there is ***no evidence*** of cause-in-fact—i.e., no evidence either that (i) had Cardinal Health done more due diligence, they would have shipped fewer orders to Cabell/Huntington pharmacies, or (ii) had Cardinal Health shipped fewer orders or terminated customers, those customers would not have obtained opioids from another distributor, or (iii) had Cardinal Health reported more orders, the DEA would have taken enforcement action. In short, there is no evidence that had Cardinal Health acted reasonably—as Plaintiffs define "reasonable"—the number of pills prescribed, dispensed, and distributed to Cabell/Huntington Could have diminished to any degree. Cardinal Health is entitled to judgment for this reason alone.

B. No Evidence of Proximate Cause

Cardinal Health adopts by reference the arguments put forward in the Memorandum of Law in Support of Defendants' Motion For Judgment On Partial Findings Regarding Proximate

[133] Trial Ex. DEF-WV-01597 at .00036; Tr. (June 9) at 168–70.

Causation, Dkt. 1440.1. As that Memorandum explains, proof sufficient to establish proximate causation requires evidence that directly connects Cardinal Health's alleged unreasonable conduct, not simply with increased addiction or overdoses, but with the derivative harm allegedly suffered by the City and County. That connection, if it can be made at all, is anything but direct.

Plaintiffs' own explanation of what caused their harm—an explanation that they have stood behind for four years, through four versions of the Complaint—does not begin with Distributors, but with Purdue Pharma and the Sackler family. According to Plaintiffs, Purdue (followed by other manufacturers) sought to expand the market for prescription opioids, and increase their profits, by promoting use of the medications for the long-term treatment of chronic pain. To that end, they deceptively marketed the medications, using eight schemes (none of them employed by Distributors) and disseminating nine misrepresentations (none of them made by Distributors). Manufacturers' deceptive marketing not only caused prescriptions to "skyrocket" over time, but also caused that increased prescribing to be perceived as consistent with the standard of care. As noted above, the Federation of State Medical Boards issued guidelines that approved the use of opioids to treat chronic pain, the DEA endorsed those guidelines, and the Joint Commission on the Accreditation of Healthcare Organizations enforced the guidelines through designating pain as the "Fifth Vital Sign."

No wonder, then, that the DEA raised the opioid quota year after year and repeatedly told Congress and the public, even as opioid use was climbing, that 99.5 percent of doctors were prescribing opioids properly, even "perfectly." But, if 99.5 percent of doctors were prescribing appropriately, then it follows that they were not diverting prescription opioids, nor were the pharmacies that filled the proper prescriptions, nor the distributors who filled the pharmacy

orders. The evidence showed that it is patients that divert the medications—by sharing or selling them, or by failing to safeguard them from theft when pills are left in the medicine cabinet. There was no evidence that patients who took the medications as prescribed, under a doctor's care, became addicted in significant numbers and contributed in any material way to Plaintiffs' alleged harm.

Accordingly, Plaintiffs claim that "suspicious" orders "more likely than not" would be diverted into the illicit market,[134] makes no sense and is entitled to no weight. Prescriptions cannot have been, at one and the same time, overwhelmingly appropriate and headed for the illicit market.

What stands between Cardinal Health's conduct in distributing prescription opioids and any harm to Plaintiffs is:

- manufacturers' deceptive marketing or prescription opioids;
- the decisions of regulatory bodies and professional societies to articulate a new standard of care for prescribing opioids;
- the medical judgment of thousands of doctors to prescribe opioids for their patients;
- the corresponding professional judgment of pharmacists to dispense the medications;
- the diversion of pills by the patients for whom they were prescribed (an illegal act);
- the further diversion of the pills by traffickers (an illegal act);
- the "non-medical use," i.e., abuse, of the pills by persons addicted to, or dependent on, opioids (an illegal act);
- the use of heroin and fentanyl (an illegal act); and
- interference with the rights of the general public of the City and County.

[134] Tr. (May 26) (Rafalski) at 104. Whether Rafalski's testimony regarding "likely diversion" is even in evidence is open to question. When Plaintiffs' counsel sought to elicit that opinion on re-direct examination, the Court twice sustained Defendants' objections. Tr. (May 27) at 46–47.

No case recognizes so attenuated a chain of causation as establishing proximate causation.[135]

III. THE COURT SHOULD ENTER JUDGMENT FOR DEFENDANTS BECAUSE PLAINTIFFS HAVE AN ADEQUATE REMEDY AT LAW

Plaintiffs seek equitable relief, and only equitable relief. It is a fundamental principle of federal equity jurisdiction, however, that a plaintiff cannot obtain equitable relief without showing the lack of an adequate remedy at law. Plaintiffs have not made that showing—and could not possibly have made that showing—for the $2 billion they seek for addiction treatment, because they pleaded a legal remedy, defended it, and then voluntarily waived it. Accordingly, under the authority of *Guaranty Trust Co. of New York v. York*, 326 U.S. 99 (1945), which has been consistently recognized and applied by the federal courts for more than a half century, judgment should be entered for Defendants.[136]

A. Plaintiffs Cannot Maintain a Claim for Equitable Relief Unless There Is No Adequate Remedy at Law

Justice Frankfurter, writing for the Court in *York*, explained that "[e]quitable relief in a federal court is of course subject to restrictions," of which there are four: (1) "the suit must be within the traditional scope of equity"; (2) any "explicit Congressional curtailment of equity powers must be respected"; (3) "the constitutional right to trial by jury cannot be evaded"; and, most familiar of all, (4) "a plain, adequate and complete remedy at law must be wanting." 326

[135] This chain, moreover, ends in harm that, as a matter of law, is an interference with the *private* right of Cabell/Huntington residents not to be negligently defrauded or injured, not any interference with a public right. *See* Dkts. 1004, 1121; Pre-Trial Conference Tr. (Mar. 18, 2021) at 6–47.

[136] Cardinal Health adopts by reference the Memorandum of Law in Support of Certain Defendants' Motion for Judgment on Partial Findings Regarding Abatement. Dkt. 1441.1, except insofar as it may suggest that West Virginia law defines the limits of federal equity jurisdiction or the scope of the equitable relief this Court can award.

U.S. at 105.[137] A federal court exercising diversity jurisdiction applies the substantive law of the state under which the claims arise, and typically employs an outcome-determination test to conclude whether a law is substantive or procedural, asking whether application of federal rather than state law would significantly affect the outcome of the litigation. But it "has long been the province ***of federal courts sitting in equity*** to apply ***a body of federal common law*** irrespective of state law." *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 839 (9th Cir. 2020) (citing *Russell v. Southard*, 53 U.S. 139, 147 (1851)). In *York*, the Supreme Court made clear that state law can neither limit nor enlarge the equitable remedies available in federal court. Whatever the state law claim, a federal court exercising diversity jurisdiction can award equitable relief—whether an injunction, restitution, disgorgement, or abatement—only if a legal remedy is inadequate.[138]

Illustrative of this requirement is the June 17, 2020 decision in *Sonner*. In that case, the plaintiff brought a putative class action alleging deceptive marketing of a nutritional product and seeking damages under California's Consumer Legal Remedies Act (CLRA) and restitution under the same Act and California's Unfair Competition Law (UCL). The plaintiff demanded a jury trial. After four years of litigation, and two months before trial, however, the plaintiff sought leave to amend the complaint to drop the CLRA damages claim. "A singular and strategic purpose drove this maneuver," the court found—"to try the class action as a bench trial

[137] In the following term, the Supreme Court again explained the equitable powers of the federal courts. In the context of relief under the Emergency Price Control Act, the Court held that the district court could order restitution of illegal rents "as an equitable adjunct to an injunction decree." *Porter v. Warner Holding Co.*, 328 U.S. 395, 399 (1946). But the Court reaffirmed that "such a recovery could not be obtained through an independent suit in equity if an adequate legal remedy were available." *Id*.

[138] West Virginia law aligns with federal equitable principles. *See Hechler v. Casey*, 333 S.E.2d 799, 805 (W. Va. 1985) ("Injunctive relief, like other equitable or extraordinary relief, is inappropriate when there is an adequate remedy at law.").

rather than to a jury" and "to request that the district court award the class $32,000,000 as restitution, rather than having to persuade a jury to award this amount as damages." 971 F.3d at 836, 838.

Over the defendant's objection, the district court granted leave to amend. *Id*. at 838. The plaintiff then filed an amended complaint that dropped the damages claim, and the defendant moved to dismiss the remaining restitution claim on the ground that plaintiff could not show that she lacked an adequate remedy at law. *Id.* The district court granted the motion to dismiss, holding that (i) California law imposed an inadequate-remedy-at-law requirement and that (ii) the plaintiff could not satisfy it. *Id.*

The Ninth Circuit affirmed. Acknowledging that the California legislature had abrogated the inadequate-remedy-at-law requirement, the court defined the "threshold jurisdictional question" as whether "federal equitable principles independently apply to Sonner's equitable claims for restitution." *Id*. at 839. In reliance on *York*, the court held that, no matter California's abrogation of the inadequate-remedy-at-law requirement, state law cannot enlarge a federal court's equitable powers. *Id*. at 841 ("[W]e hold that a federal court must apply traditional equitable principles before awarding restitution under the UCL and CLRA. It has been a fundamental principle for well over a century that state law cannot expand or limit a federal court's equitable authority.").

Turning to the "rigid restrictions" enumerated in *York* that constrain a federal court's equitable powers, *id.* at 842, the court in *Sonner* further held that "the traditional principles governing equitable remedies in federal courts, including the requisite inadequacy of legal remedies," applied to the plaintiffs' restitution claims. *Id*. at 844. Under these principles, the court stated, "Sonner must establish that she lacks an adequate remedy at law before securing

equitable restitution for past harm under the UCL and CLRA." *Id*. She failed to make that showing, however, having failed both (i) to allege in the operative complaint that she lacked an adequate legal remedy and (ii) to explain "how the same amount of money for the exact same harm is inadequate or incomplete." *Id*. She plainly had an adequate remedy because she pled, then voluntarily dismissed, her CLRA claim for damages for the "singular and strategic purpose" of "try[ing] the [case] as a bench trial rather than to a jury." *Id*. at 836.

The Ninth Circuit noted that its decision "mirrors those of several other circuits," including the Fourth Circuit, *SSMC, Inc. v. N.V. Steffen*, 102 F.3d 704, 708 (4th Cir. 1996). In the short time since the Ninth Circuit decided *Sonner*, twelve district courts have applied its holding to dismiss claims for equitable relief.[139]

B. Plaintiffs Have an Adequate Remedy at Law

The *Sonner* holding applies here. The facts here and in *Sonner* are uncannily similar. As in *Sonner*, Cabell County and the City of Huntington: (1) filed a complaint (indeed, an original complaint plus three amended complaints) that alleged an array of claims and sought both damages and equitable relief; (2) more than three years later and after extensive discovery from Defendants, moved to sever all defendants except the three Defendants, voluntarily dismissed all claims except public nuisance (including the RICO and negligence claims), and disclaimed damages; and (3) executed this maneuver for the two-fold strategic purpose of securing an early

[139] *See Sharma v. Volkswagen AG*, 2021 WL 912271 (N.D. Cal. March 9, 2021); *Heredia v. Sunrise Senior Living LLC*, 2021 WL 819159 (C.D. Cal. Feb. 10, 2021); *Huynh v. Quora, Inc.*, 2020 WL 7495097 (N.D. Cal. Dec. 21, 2020); *Williams v. Apple, Inc.*, 2020 WL 6743911 (N.D. Cal. Nov. 17, 2020); *IntegrityMessageBoards.com v. Facebook, Inc.*, 2020 WL 6544411 (N.D. Cal. Nov. 6, 2020); *In re: MacBook Keyboard Litig*., 2020 WL 6047253 (N.D. Cal. Oct. 13, 2020); *Gibson v. Jaguar Land Rover N. Am., LLC*, 2020 WL 5492990 (C.D. Cal. Sept. 9, 2020); *Adams v. Cole Haan LLC*, 2020 WL 5648605 (C.D. Cal. Sept. 3, 2020); *Alvarado v. Wal-Mart Associates, Inc.*, 2020 WL 6526372 (C.D. Cal. August 7, 2020); *Schertz v. Ford Motor Co*., 2020 WL 5919731 (C.D. Cal. July 27, 2020).

remand of the case from the MDL proceedings and obtaining a bench trial. Plaintiffs did all this, moreover, without ever alleging that they lacked an adequate remedy of law.

The record of Plaintiffs' allegations and argument makes clear that Plaintiffs do indeed have an adequate remedy at law.

First, Plaintiffs alleged a remedy at law. They brought RICO and negligence claims that sought to recover damages for the harm allegedly caused to Cabell/Huntington by Defendants' conduct, specifically harm in the form of increased addiction and overdose events. Although Plaintiffs now seek only equitable relief pursuant to their public nuisance count, that count (as alleged in all versions of the Complaint) seeks both equitable relief and damages. Moreover, both the public nuisance and negligence counts have the same factual predicate. The Complaint alleges as Plaintiffs' principal harm the epidemic of addiction and overdose deaths in Cabell/Huntington,[140] and both the nuisance and negligence counts allege—in identical language—that Plaintiffs "have suffered and will continue to suffer" the costs of providing addiction treatment and related medical services. *Compare* TAC ¶ 1437 ("As a direct and proximate result of Defendants' ***tortious conduct and the public nuisance*** created by Defendants, Plaintiffs have suffered and will continue to suffer economic damages, including … significant expenses for … health, … rehabilitation, and other services") *with* ¶ 1548 ("As a direct and proximate result of Defendants' ***negligence and/or negligence per se***, Plaintiffs have suffered and will continue to suffer economic damages, including … significant expenses for … health, … rehabilitation, and other services"). Similarly, the RICO claim alleges that Plaintiffs' injuries include "[c]osts for providing healthcare and medical care, additional therapeutic, … and

[140] TAC ¶¶ 1149–50 ("The State had the highest drug-overdose death rate"); ¶ 1151 ("West Virginia leads the nation in opioid deaths and has a drug addiction problem that is devastating families and communities across the state").

other treatments for patients suffering from opioid-related addiction and disease;" "costs for providing mental-health services, treatment, counseling, rehabilitation services;" and "costs for providing treatment of infants born with opioid-related medical conditions"). *Id*. at ¶ 1475.

Second, Plaintiffs maintained that their claims for damages were valid legal claims. When Defendants moved to dismiss the complaint in 2017, Plaintiffs argued in opposition that they had asserted valid claims for damages for the "foreseeable harm" of diversion and its consequences—i.e., "abuse, addiction, morbidity and mortality." Dkt. 61 at 20. Plaintiff headed one section of their Response, "Plaintiffs' Complaints Plausibly Allege Damages," and under that heading, they argued more specifically: (1) "The Free Public Services Doctrine does not bar Plaintiffs' claims;" (2) "Plaintiffs' damage claims are not barred by the economic loss rule;" and, notably, (3) "Plaintiffs' damages are not limited to abatement." *Id*. at 38, 44, 47. Plaintiffs argued that the ability of a governmental entity to bring a public nuisance claim for damages was "not in doubt." *Id*. at 48. And they cited in support of their argument the decision of the Boone County Circuit Court denying Defendants' similar motion to dismiss and quoted its holding that Plaintiffs had asserted a viable claim for future damages. *Id*. at 46 & n. 149 ("it is foreseeable the conduct alleged … is sufficiently likely to result in the [government] having to spend ***additional resources*** to combat the escalation of the prescription drug epidemic").

Third, even after disclaiming their right to seek damages in this case, Plaintiffs continued to maintain their authority to sue for damages. In opposing Defendants' summary judgment motion based on lack of standing, Plaintiffs argued that Cabell/Huntington's authority to seek redress for a public nuisance is not limited to those sections of the West Virginia Code that specifically delegate authority to abate public nuisances. Plaintiffs asserted that "[t]he Supreme Court has broadly interpreted the modern powers of political subdivisions and rejected the

proposition that county and municipal power is limited to strictly construed express powers." Dkt. 287 at 14. Indeed, plaintiffs argued that the modern provisions of the municipal code grant cities "plenary power and authority" in matters involving "public services, police power, public safety, and health and safety," *id*. at 13—thus, authority that would include the right to sue for past and future damages. In addition to the record of Plaintiffs' own allegations and arguments in this case, the record in the wider opioid litigation makes clear that Plaintiffs have an adequate remedy at law.

Fourth, it is a matter of historical fact that the State of West Virginia sued Defendants, seeking damages for allegedly creating a public nuisance and for negligence. The State alleged that the damage to the health of West Virginia citizens from the alleged nuisance had occurred "in the past and will continue to do so in the future" and that it had sustained economic harm and "will continue to suffer economic harm."[141] The State settled those claims for present and future damages (and abatement) for tens of millions of dollars.

Fifth, now before the West Virginia Mass Litigation Panel are numerous similar lawsuits against Defendants, all of which allege damages.[142] The Panel has denied Defendants' motion to

[141] Am. Compl. ¶¶ 54–55, *State of West Virginia v. Cardinal Health, Inc*., No. 12-C-140 (W.Va. Cir. Ct.).

[142] *See*, *e.g*., Compl. ¶ 230, *County Comm'n of Mason County, et al. v. Purdue Pharma, L.P., et al.*, C.A. Nos. 19-C-4, 5, 6, 7, 8, 9 ("The damages incurred by Plaintiffs include … money expended on … emergency healthcare and medical services, drug abuse education and treatment …."); *id*. at ¶ 293 ("Plaintiffs have sustained economic harm in the expenditure of massive sums of monies and will continue to suffer economic harm in the future …."); *id*. at 67 (Prayer seeking "a jury trial on all issues so triable to determine damages").

dismiss, holding that "the Complaint sufficiently states claims upon which relief can be granted."[143]

Sixth, the MDL denied Defendants' motion to dismiss the Track 1 cases brought by the City of Cleveland and Cuyahoga County—cases that mirrored the allegations and claims made by Plaintiffs here. In denying the motion to dismiss, Judge Polster recognized that the Cuyahoga/Cleveland plaintiffs "assert thirteen categories of damages," including for "providing healthcare and medical care … and other treatments for patients suffering from opioid-related addiction or disease." And he found that the plaintiffs' "alleged damages are not speculative, but concrete and ascertainable" and that "[n]o other party can vindicate the law and deter Defendants' alleged conduct because Plaintiffs' asserted damages are not recoverable by any other party."[144]

In sum, Plaintiffs' allegations, arguments, and admissions in this case, as well as the allegations, arguments, and rulings made in the wider litigation, show that Plaintiffs have an adequate remedy at law for the $2 billion they seek to provide medical care in the form of addiction treatment and related services.[145]

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[143] Order Regarding Defendants AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation's Motion to Dismiss (Feb. 5, 2020), *County Comm'n of Mason County v. Purdue Pharma, L.P.*

[144] Opinion and Order, *In re: National Prescription Opioid Litig.*, MDL-2804, Dkt. 1203 (Dec. 19, 2018) at 10, 15.

[145] Plaintiffs cannot argue that they lack an adequate remedy at law because they waived recovery of damages. *Sonner* forecloses that argument, which is akin to the patricide-matricide who throws himself on the mercy of the court because he is an orphan. *See also United States v. Elias*, 921 F.2d 870, 874 (9th Cir. 1990) ("Failure to comply with a remedy at law does not make it inadequate so as to require the district court to exercise its equitable jurisdiction.").

The test of adequacy is not whether the plaintiff would have recovered damages had he pursued a legal remedy. Rather, it is whether the plaintiff has potential legal claims. *See, e.g.*, *McKesson HBOC, Inc. v. New York State Common Ret. Fund, Inc.*, 339 F.3d 1087, 1093 (9th Cir. 2003) (holding that equitable relief was not available to plaintiff because it had "potential legal claims against any number of parties," and "[w]hether [a plaintiff] chooses to pursue these remedies… does not alter the availability of the remedies at law.").[146] The costs of medical treatment are classic damages. Where the personal injury is semi-permanent or permanent and medical costs will extend into the future, damages can be recovered to cover those future costs as well as past medical expenses. Dobbs, Law of Remedies (3d ed.) § 8.1(3) ("*General Rule*: The value of medical and related treatment reasonably necessary to minimize or alleviate injury itself or the pain or disability that results from it are almost always recoverable as items of damages …. In the same way, plaintiff is entitled to recover the value of treatment or care likely to be reasonably necessary in the future.").

Thus, regarding the $2 billion Plaintiffs seek for future addiction-related treatment, they unquestionably had an adequate legal remedy, but for strategic reasons voluntarily relinquished

[146] *See also Rhynes v. Stryker Corp.*, 2011 WL 2149095, at *4 (N.D. Cal. May 31, 2011) ("Plaintiffs' argument that they will have no adequate remedy at law if their other claims fail is unavailing. Where the claims pleaded by a plaintiff *may* entitle her to an adequate remedy at law, equitable relief is unavailable." (emphasis in original)); *Hassell v. Uber Techs., Inc.*, 2020 WL 7173218, at *9 (N.D. Cal. Dec. 7, 2020) (dismissing on *Sonner* grounds where plaintiff had legal remedies available but failed to pursue them); *Robinson v. C.R. Bard, Inc.*, 2016 WL 3361825, at *3 (N.D. Cal. June 17, 2016) (dismissing UCL claim because an adequate remedy at law existed through the "compensatory damages" sought by the plaintiff, even though all legal claims were simultaneously dismissed as barred by the statute of limitations).

it. The holdings in *York* and *Sonner* dictate that the Court grant judgment for Defendants as to the $2 billion Plaintiffs seek in future medical costs.[147]

IV. THE COURT SHOULD ENTER JUDGMENT FOR DEFENDANTS BECAUSE PLAINTIFFS HAVE NOT ESTABLISHED A LEGAL ENTITLEMENT TO EQUITABLE *MONETARY* RELIEF

This much is uncontested: Plaintiffs have waived damages; they seek only equitable relief. The "rub" is that the equitable relief they seek is beyond the power of the Court to grant for two reasons. First, as explained in Part III (above), a federal court cannot provide equitable relief unless the plaintiff has established that it lacks an adequate remedy at law, and Plaintiffs have not established (and cannot establish) that for the $2 billion they seek for addiction treatment and related services. Second, as we explain here, a federal court cannot award monetary relief (apart from restitution or disgorgement, which Plaintiffs do not seek) except ***adjunct*** to injunctive relief, which Plaintiffs also do not seek.[148]

A. The Court Lacks Equitable Power Under Federal Common Law to Grant Exclusively Monetary Relief

Three Supreme Court decisions help explain the limits of federal court equity jurisdiction. In *Guaranty Trust Co. v. York*, as noted above, the Court held that "[e]quitable relief in a federal court is of course subject to restrictions," the first of which is that "the suit must be within the traditional scope of equity as historically evolved in the English Court of Chancery." 326 U.S. at 105. "State law cannot define the remedies which a federal court must give simply because a federal court in diversity jurisdiction is available as an alternative tribunal to the State's courts." *Id*. at 106.

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[147] For different reasons, Plaintiffs' claim for the remaining $0.6 billion in relief is infirm as a matter of law and should be denied. *See* Part V, *infra*.

[148] The same is true under West Virginia law, if it governed. It does not, as explained in Part I.

The following year, in *Porter v. Warner Holding Co.*, 328 U.S. 395 (1946), addressed the traditional scope of equity. In that case, which involved a federal court's power to order the restitution of rents collected in violation of the Emergency Price Control Act of 1942, the Supreme Court held that an order for the restitution of illegal rents was proper under two theories. It could be considered proper "as an order appropriate and necessary to enforce compliance with the Act." *Id*. at 400. And, as a matter of traditional equity jurisdiction, it could also be considered proper "as an equitable ***adjunct*** to an injunction decree." *Id*. at 399. The Court noted that, "[t]o be sure, such a [monetary] recovery could not be obtained through an independent suit in equity if an adequate legal remedy were available." *Id*. But a federal court has the power "to award complete relief" where "the equitable jurisdiction of the court has properly been invoked ***for injunctive purposes***." *Id*.

In 1993, in *Mertens v. Hewitt Associates*, 508 U.S. 248, the Supreme Court again addressed the traditional scope of equitable relief. Arguing that ERISA § 502(a)(3) permits pension plan participants to obtain "appropriate equitable relief," the plaintiffs sought to hold a non-fiduciary actuary responsible for losses suffered by the plan. In affirming dismissal of the claim, the Court said:

> Petitioners maintain that the object of their suit is "appropriate *equitable* relief" under § 502(a)(3) (emphasis added). ***They do not, however, seek a remedy traditionally viewed as "equitable," such as an injunction or restitution***. … Although they often dance around the word, what petitioners in fact seek is nothing other than compensatory *damages*—monetary relief for all losses their plan sustained as a result of the alleged breach of fiduciary duties.

Id. at 255.

The same is true here: Plaintiffs do not seek a remedy traditionally viewed as equitable. Abatement is a traditional equitable remedy, of course, but Plaintiffs do not seek abatement in its

traditional sense.[149] They do not ask the court to enter an order requiring Defendants to cease or suspend any activity or to remove or diminish any problem. Their objective is not to command Defendants to ***do*** or ***refrain from doing*** anything; it is only to have Defendants pay a sum of money. It is as true of Plaintiffs here as it was of the plaintiffs in *Mertens* that "they often dance around the word, [but] what [they] seek in fact is nothing other than compensatory *damages*." Unlike in *Porter v. Warner Holdings*, however, they do not seek monies "as an equitable adjunct to an injunction decree."

From the earliest days of the Republic, the federal courts sitting in equity have applied a body of federal common law irrespective of state law. *Russell v. Southard*, 53 U.S. 139, 147 (1851) (holding that "this court must be governed by its own views of those principles [of general equity jurisprudence]," not those of any state); *Sonner v. Premier Nutrition Corp.*, 971 F.3d 834, 839 (9th Cir. 2020) (citing *Russell*). What is so telling in this case is that Plaintiffs have never cited—and cannot cite—***any federal court decision that has ordered as an equitable remedy the relief Plaintiffs seek here***—i.e., an award of money alone, not adjunct to an injunction, and in principal part for medical treatment (i.e., classic damages).

[149] *See State v. AmerisourceBergen Drug Corp.*, Nos. 20-0694 & 20-0751 (June 11, 2021) (Hutchison, J., concurring) ("'Abatement' is an equitable form of relief and is simply the 'act of eliminating or nullifying' whatever is causing the public nuisance.") (quoting Garner, Black's Law Dictionary (11th ed. 2019)); *see* E.R. Hardy Ivamy, Mozley & Whiteley's Law Dictionary (11th ed. 1983) (defining "Abatement of nuisances" as "their removal"); Dictionary of Law (5th ed. 2007) (defining "abatement" as "the legal right to remove or stop a nuisance"); Merriam-Webster's Dictionary of Law (2011) (defining "abate" as "to put an end to or do way with (~ a nuisance)"); J. Law, Dictionary of Law (8th ed. 2015) (defining "abatement (of nuisances)" as the "termination, removal, or destruction of a nuisance"); S. Giftis, Law Dictionary (7th ed.) (defining "abatement of a nuisance" as "the removal, termination or destruction of a nuisance by self help").

The total absence of such precedent is not because the nature of this litigation is unique. Plaintiffs are fond of drawing an analogy between pollution and the opioid problem.[150] But reported federal cases involving toxic waste sites and the like are common, and in none of them have the federal courts ordered the payment of money, not adjunct to an injunction (and certainly not when the money is to pay for medical treatment for personal injuries). When plaintiffs in these cases sue regarding the polluted property itself, they seek to enjoin the polluting conduct and to require clean-up of the property. If the plaintiffs receive monies, it is as damages for past clean-up costs, and, if the defendants pay out monies, it is incidental to the clean-up injunction. On the other hand, when occupants of the property or nearby residents sue for personal injuries allegedly caused by the pollution and seek compensation for past and future medical costs, there is no talk of "abatement;" they seek damages pursuant to product liability, negligence, or private nuisance theories.

The precedent to which Plaintiffs have always pointed the Court is *People v. ConAgra Grocery Prod. Co.*, 17 Cal. App. 5th 51, 227 Cal. Rptr. 3d 499 (Ct. App. 2017).[151] But, as a decision of a California state court applying California law, *ConAgra* has nothing relevant to say about federal equity jurisdiction. *Guaranty Trust Co. v. York*, 326 U.S. at 106 ("State law cannot define the remedies which a federal court must give …."); *Sonner*, 971 F.3d at 841 ("It has been a fundamental principle for well over a century that state law cannot expand or limit a federal court's equitable authority.").[152]

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[150] The analogy is imperfect, at best, for reasons it is unnecessary to explore here.

[151] Dkts. 267 at 7; 1083 at 11.

[152] *ConAgra* concerned lead-paint poisoning. Notably, while the state court ordered the defendants to pay money into a fund, the purpose of the fund was to pay for lead-paint *removal*, not for the costs of past or future medical care or assistance for the children injured by lead paint.

After four years of litigation, to what other authority can Plaintiffs point? When Plaintiffs sought to persuade the Court that defendants were not entitled to a jury trial and that "injunctive relief provided to abate a nuisance … is equitable," they cited 18 cases.[153] Note the concession that it is "***injunctive relief*** provided to abate a nuisance" that is equitable. Not surprisingly, then, the 18 cases provide no precedent for an award of monetary relief not incident to an injunction. Of the 18, eight were state court decisions and, like *ConAgra*, irrelevant to the issue whether a federal court has the power to award "equitable" relief that is money alone. Of the ten federal court decisions, none ordered an award of money apart from injunctive relief, and none ordered an award of money for medical treatment (or anything like it). Indeed, of the ten federal court decisions, two concerned the seizure of automobiles,[154] four sought only injunctive relief and/or equated abatement with injunctive relief,[155] and two disagree as a matter of

[153] Plaintiffs' Mem. in Support of Nonjury Trial (Dkt. 267), p. 9. There has never been any dispute, of course, that "*injunctive relief* provided to abate a nuisance … is equitable." But Plaintiffs do not seek injunctive relief of any kind.

[154] *Bennis v. Michigan*, 516 U.S. 442 (1996) (prosecutor alleged that car used for prostitution was a public nuisance subject to abatement, i.e., forfeiture); *Conner v. City of Santa Ana*, 897 F.2d 1487 (9th Cir. 1990) (describing seizure by police of illegally parked cars as "proceeding to abate a nuisance").

[155] *Michigan v. U.S. Army Corps of Engineers*, 667 F.3d 765 (7th Cir. 2011) (suit to enjoin Corps of Engineers project that would harm endangered species); *West-Morgan-East Lawrence Water & Sewer Auth. v. 3M Co.*, 208 F. Supp.3d 1227 (N.D. Ala. 2016) (citing Alabama law for the proposition proof of negligence is required "to sustain injunctive relief ordering abatement"); *Citizens for Alternatives to Radioactive Dumping v. Cast Transportation, Inc.*, 2004 WL 7338006 (D.N.M. 2004) (suit for permanent injunctive relief); *National Ass'n For the Advancement of Colored People v. Acusport Corp.*, 226 F. Supp.2d 391, 396 (E.D.N.Y. 2002) (suit for injunctive relief, including restrictions on the method of sale and transfer of guns, and adjunct "funds to help abate");

California law about an issue not relevant here (i.e., whether a plaintiff that has brought a continuing-nuisance claim can recover post-filing, pre-judgment ***damages***).[156]

The remaining two cases support Defendants' position that, in exercising its equitable powers, the federal court cannot award monetary relief apart from, and in aid of, injunctive relief. In *U.S. v. Wade*, 653 F. Supp. 11 (E.D. Pa. 1984), the issue was whether certain defendants were entitled to a jury trial on the Commonwealth's nuisance claim. The court held that "clearly" the "request for an injunction directed towards abatement of the alleged nuisance constitutes equitable relief." *Id*. at 13. "More difficult is [the] request for monetary relief," the court said. *Id*. But because the Commonwealth sought recovery only of past costs ("its costs incurred in abating the nuisance"), the court determined that the monetary relief was "in the nature of equitable restitution." *Id*. Here, of course, Plaintiffs have disclaimed recovery of all past costs and do not seek restitution. Similarly, in *New York v. West Side Corp.*, 790 F. Supp.2d 13, 16, 29 (E.D.N.Y. 2011), which "involve[ed] costs incurred by the state in responding to hazardous substances released" at a storage distribution center, the court stated that "[t]here are two possible forms of relief available on this [public nuisance] cause of action, but the one seeking pure monetary damages cannot be characterized as equitable." Cost recovery must be distinguished, the court explained, from "injunctive relief that might be sought for a cleanup yet to come." *Id*.at 30. The court allowed for the possibility of awarding monies for future cleanup only in the unusual circumstance of contempt:

> Hypothetically, if a court were to order defendants to undertake additional remediation efforts at the site, and, ***in defiance of such***

[156] Both decisions are unreported in the federal reporter. *San Diego Unified Port District v. Monsanto Co.*, 2018 WL 4185428 at *5 (S.D. Cal. 2018) (noting that "'[a]n abatement of a nuisance is accomplished by a court of equity by means of an injunction proper and suitable to the facts of each case'"); *Orange Co. Water District v. Unocal Corp.*, 2016 WL 11201024 (C.D. Cal. 2016).

> ***an order, defendants refused to do so***, that court could conceivably authorize the state to remediate the site further and obtain equitable relief from defendants in the form of compensation for the costs incurred by the state to comply with the equitable order in the stead of the defiant defendants.

Id. That circumstance—the hypothetical case where (i) the court issues an injunction that (ii) the defendant defies, (iii) only "conceivably" authorizing the court to order reimbursement of the plaintiff—is a far cry from what Plaintiffs seek here, which is the (i) payment of billions of dollars (ii) in the first instance (iii) absent any injunction.

Later, in opposing Defendants' motion for summary judgment regarding abatement,[157] Plaintiffs again cited the California *ConAgra* decision, plus four additional cases. Two were state cases, and therefore irrelevant to the federal court's equity jurisdiction. The third case, *In re Peabody Energy Corp.*, 958 F.3d 717 (8th Cir. 2020), had to do with whether the plaintiff-municipalities' California public nuisance claims could be discharged in bankruptcy. That question turned on whether California law permitted relief that included a payment of money, and the court, citing *ConAgra*, held that it does.[158] *In re Peabody* says nothing about the federal court's equitable power. Nor does the fourth case cited by Plaintiffs, *United States v. Price*, 688 F.2d 204 (3d Cir. 1982), support their claim for purely monetary relief. In *Price*, the Third Circuit affirmed the ***denial*** of preliminary injunctive relief that would have required the defendants to pay for a diagnostic study as "the first step in the remedial process of abating an existing but growing toxic hazard." *Id*. at 212. In dicta, the court allowed that it would have

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[157] Dkt. 1083. Defendants' motion was based on the testimony of the County Administrator that the County had taken no steps to abate the alleged public nuisance because abatement activities were "not a function of county commission government." Dkt. 1005.1 at 4.

[158] Unlike here, the plaintiff-municipalities in *In re Peabody* did not seek the payment of any monies into the public treasury. 958 F.3d at 724–25 ("The municipalities point out that they would not receive the proceeds that a court directs to be paid into an abatement fund; that money, unlike damages, would go to a receiver.").

been within the district court's equitable power to order funding of the study, but: (1) payment for the study would have been adjunct to ultimate, broader injunctive relief; (2) the United States was suing pursuant to federal statutes that "enhanced the courts' traditional equitable powers," *id*. at 211; and (3) the court distinguished its prior decision in *Jaffee v. United States*, 592 F.2d 712 (3d Cir. 1979), where the requested payments for medical treatment (as here) were not adjunct to primary injunctive relief and were properly viewed as "a traditional form of damages in tort," *id*. at 212; *Jaffee*, 592 F.2d at 715 ("A plaintiff cannot transform a claim for damages into an equitable action by asking for an injunction that orders the payment of money. … Jaffee requests a traditional for or damages in tort compensation for medical expenses to be incurred in the future.").

If federal courts have the power in equity to grant purely monetary relief—in the billions of dollars, per Plaintiffs' request—then there should be precedent in the 200-year history of the Republic for the exercise of such power. Plaintiffs have cited none. [159]

V. THE COURT SHOULD ENTER JUDGMENT FOR DEFENDANTS BECAUSE PLAINTIFFS HAVE NOT MATCHED THE EQUITABLE REMEDY TO THE WRONG

The Court has broad discretion in exercising its equitable powers. But the Fourth Circuit, using different terminology at different times, has consistently emphasized that the remedy must be narrowly tailored to fit the wrong. *Mayor of Baltimore v. Azar*, 973 F.3d 258, 293 (4th Cir. 2020) (quoting *Swann v. Charlotte-Mecklenburg Bd. of Educ*., 402 U.S. 1, 16 (1971)) ("As with

[159] Even if West Virginia law defined the scope of this Court's equitable power, it is well-established under West Virginia law that (1) a public nuisance consists of conduct that, *inter alia*, injuriously affects the public health or safety, and (2) abatement consists of eliminating or otherwise addressing that conduct. Equitable abatement under West Virginia law does not include compensation for downstream harm to individuals caused by the allegedly tortious conduct. *See* Part I, Memorandum of Law in Support of Certain Defendants' Motion for Judgment on Partial Findings Regarding Abatement.

any equity case, the nature of the violation determines the scope of the remedy."); *Casa de Maryland, Inc. v. Trump*, 971 F.3d 220, 256 (4th Cir. 2020) (explaining that the court's "power to grant equitable remedies is commensurate with" the duty to settle particular cases or controversies and so "Article III requires that injunctions be tailored to protect only the plaintiffs in a specific case from the defendants to that suit"); *Ostergren v. Cuccinelli*, 615 F.3d 263, 289 (4th Cir. 2010) (noting both that "a federal court is required to tailor the scope of the remedy to fit the nature and extent of the constitutional violation" and that "a remedy must be narrowly tailored"); *Kentuckians for Commonwealth, Inc. v. Rivenburgh*, 317 F.3d 425, 436 (4th Cir. 2003) ("[a]n injunction should be carefully addressed to the circumstances of the case" and "should not go beyond the extent of the established violation"); *see* Dobbs, Law of Remedies (3d ed.) § 1.7 ("Remedial Analysis: Matching Right and Remedy").

Plaintiffs' request for $2.5 billion to fund a variety of programs[160] is heedless of this legal principle. Of that number, $2 billion is for addiction treatment and medical services for HIV, hepatitis C, and endocarditis.[161] As explained in Part III, the Court lacks equitable jurisdiction to award that amount (or any amount), because Plaintiffs have an adequate legal remedy. Even if they did not, the $2 billion proposed for addiction and infectious disease treatment is not a figure narrowly tailored to fit the wrong for three reasons. First, some substantial (but unknown) proportion of the $2 billion is for treatment of Cabell/Huntington residents who developed Opioid Use Disorder ("OUD") after 2013.[162] There is no record evidence that Cardinal Health

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[160] Tr. (June 29) (Barrett) at 106, *see also id.* at 106-11 (costs of components of Plaintiffs' plan), 130-41 (present value of components of Plaintiffs' plan). Prorating the 2021 numbers to start from September 1, 2021, the present value of this sum is $1.8 billion. *Id.* at 115–16.

[161] Tr. (June 29) (Barrett) at 174–75.

[162] Tr. (June 29) (Barrett) at 197 ("Q. And, likewise, if we look backwards and if we said how much of this cost is for people who had OUD as of 2016 or 2015 or 2013 or any year, you

engaged in unreasonable conduct after 2013.[163] Second, some substantial (but also unknown) proportion of the $2 billion is for treatment of ***future*** addiction—that is to say, for Cabell/Huntington residents who are not addicted even now and who, ***if*** they become addicted in the future, will not do so by reason of suspicious orders that Cardinal Health allegedly did not report or block in the pre-2013 era.[164] Third, some substantial (but also unknown) proportion of the $2 billion is for treatment of people who never used prescription opioids at all but only illicit opioids.[165]

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don't have a way to determine how much of the cost is allocated that way? A. I do not, no. I'm relying on Dr. Alexander's opinions on those matters."); *see also* Tr. (June 28) (Alexander) at 153 ("Q. So, you've not estimated how many people would develop OUD each year during the period covered by your model, correct? A. Right. I've not – I've not estimated the proportions that are developing opioid addiction anew in each subsequent year.").

[163] Cardinal Health submits that Plaintiffs have failed to prove that it engaged in unreasonable conduct (i.e., unreasonably interfered with a public right) at any time. *See* Part I. For purposes of the argument that follows, however, we assume that Plaintiffs have met their burden of proof for the period before 2013, and references to Cardinal Health's "unreasonable conduct" or "conduct" reflect that assumption. Plaintiffs have not sought to prove, and there is no evidence, that Cardinal Health engaged in unreasonable conduct after 2013.

[164] Tr. (June 28) (Alexander) at 150 ("Q. And you also assume that there are new people who develop OUD over the 15-year period covered by your redress model in addition to your starting population, correct? A. Yes."), 151–52 ("Q. And that might include—just as an example, that could include a child who is ten years old as of 2021 and has never used opioids begins abusing heroin in 2027 as a teenager and develops OUD. That … child would be included in your OUD numbers, correct? A. It would…."), 153–54 ("Q. So, there's no way to separate out the group that has newly developed OUD after 2021, as compared to the group that had OUD as of 2021? That hasn't been done in this case? A. It hasn't because I focused on abating the overall opioid epidemic …. It's not necessary from a public health and public policy perspective.").

[165] Tr. (June 28) (Alexander) at 119–20 ("Q. Is it correct that the abatement plan you set forth would provide services and treatment to individuals who never took prescription opioids? A. Yes, it is. Q. And do you agree … that there are individuals in [Cabell/Huntington] who have OUD who have, in fact, never used a prescription opioid? A. Yes, I do."); *see also id.* at 120–21 (Alexander confirming that his abatement plan would cover people who had only ever used illegal opioids like heroin, illegal fentanyl, or carfentanil).

The same is true for the more than $500 million Plaintiffs seek for a variety of programs ***other than*** for addiction or infectious disease treatment. Some substantial sum is for Cabell/Huntington residents (in unknown numbers) who (1) were not addicted as of 2013, (2) are not now addicted, but may become addicted in the future, and (3) have OUD, but may never have used prescription opioids.

Because the alleged wrong is Cardinal Health's failure to block shipment of suspicious pharmacy orders, arguably leading by a series of steps to increased levels of opioid addiction among Cabell/Huntington residents, a narrowly tailored remedy—one consistent with the traditional definition of "abatement"—would enjoin the shipment of suspicious orders and/or mandate certain types of suspicious order monitoring. (This assumes that the unreasonable conduct continues to this day, which it does not; indeed plaintiffs do not allege that it continues).

Even if a narrowly tailored "abatement" remedy could include treatment costs and other medical-intervention programs (it cannot, *see* Part III), that abatement remedy should extend only to those Cabell/Huntington residents who became addicted by reason of those ***past*** pharmacy orders that Cardinal Health should have blocked. But Plaintiffs seek unspecified millions of dollars (likely hundreds of millions) in relief for residents who—if they become addicted in the future—may become addicted, not to prescription opioids, but to illegal drugs.[166] Plaintiffs also seek millions for educating doctors about proper prescribing of opioids, although Cardinal Health's conduct had nothing to do with the standard of care that encouraged over-prescribing. They seek millions for educating children about drug abuse including for addressing "the ripple effects throughout families and the intergenerational effects" that may lead to drug

[166] *See* n.164, *supra*.

abuse,[167] although these children and adolescents may not yet have been born at the time Defendants were allegedly shipping suspicious orders. And Plaintiffs seek millions for community-oriented policing, counseling for mental illness, permanent supportive housing, and programs (i) for persons released from prison, (ii) to train more healthcare workers, (iii) to reduce homelessness, and (iv) even a program to check the content of illegal drugs for fentanyl[168]—and all this regardless of whether the beneficiaries became addicted to prescription opioids that were "over-supplied" by Cardinal Health.[169]

Plaintiffs also intend for their remedy to provide assistance to people who do not suffer from addiction at all. According to Dr. Alexander, "recovery includes a whole host of programs and services that aren't focused … directly on treating individuals with active addiction, but nevertheless will allow for those individuals to flourish and for the community as a whole to regain its former livelihood and standing that Cabell County and the City of Huntington historically have had."[170] Following from this premise, Plaintiffs' plan calls for activities ranging from "help[ing] employers to better manage the workplace and to help local businesses

[167] Tr. (June 28) (Alexander) at 143–44 ("Q. Category 4-B, Adolescents and Young Adults, that addresses the impact of opioid use, addiction and overdoses on children and adolescents, correct? A. Yes, including the ripple effects throughout families and the intergenerational effects that I spoke to briefly earlier."); *see also id.* at 139 ("I mean, again, if you think about the need for social workers in the school system, they're not there necessarily to treat teenagers that have Opioid Use Disorder, although there may be such teenagers …. My point is that this is a much bigger problem than just a problem of addiction alone.").

[168] *Id*. at 136.

[169] *Id*. at 121, 153–54 ("… I focused on abating the overall opioid epidemic and, for that purpose, such a separation or sort of distinction of one population versus another is -- is, in some sense, immaterial. It's not necessary from a public health and public policy perspective.").

[170] *Id*. at 59.

to thrive"[171] to assisting people who are "suicidal and thinking about ending their lives because of the trauma that they have experienced with family members that may have active addiction."[172]

Alexander provided remarkably little explanation about the content or necessity of the programs he proposed, or how much would be spent on them. About the $212 million for "families and children," he said only that the sum "includes services both to support children that may be living in households where there's a lot of chaos because of the ongoing addiction, as well as children, for example, that may have a history of Neonatal Abstinence Syndrome in the past and their families."[173] He said nothing about what specific programs would be funded with that $212 million, or why $212 million is the right number. Plaintiffs ask the Court to accept Alexander's say-so that these are the right amounts for programs that have labels, but not definition.

Two historical facts betray the shoot-the-moon nature of Plaintiffs' proposed remedy. First, when the Attorney General pursued these same allegations against Defendants on behalf of the State and, in the State's *parens patriae* capacity, on behalf of ***all*** the State's citizens, it settled the litigation for $73 million.[174] Second, when Plaintiffs' counsel invited Marshall University to assemble a group of local leaders to devise a cost-is-no-consideration "resiliency plan" for the community, the group proposed a roughly $500 million plan that would run for 40 years and

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[171] *Id*. at 61.

[172] *Id* at 138.

[173] Tr. (June 28) (Alexander) at 66; *see also id.* at 144; Tr. (June 29) (Barrett) at 176–77.

[174] https://www.reuters.com/article/us-usa-opioids-litigation/mckesson-to-pay-37-million-to-resolve-west-virginia-opioid-lawsuit-idUSKCN1S81HO.

spend 70 percent of that sum on a research institute, economic development, housing, and transportation.[175]

As explained below, much of the more than $500 million that Plaintiffs seek for relief other than addiction and infectious disease treatment falls into four categories, each of which violates the principle that an equitable remedy must be narrowly tailored to the wrong.

A. Remedies For the Wrongs of Others

Plaintiffs seek more than $200 million for remedies that having nothing to do with the distribution of prescription opioids generally, or Cardinal Health's alleged conduct specifically.

For example, Plaintiffs seek $5.5 million for educating (or re-educating) doctors about proper prescribing of opioids, including through paying doctors to attend continuing education seminars and providing individual tutorials four times per year.[176] But there is no evidence that Cardinal Health conceived or disseminated any false or misleading messages about prescription opioids. Manufacturers do that, and what Plaintiffs allege at great length (and thereby admit) is that it was the ***Manufacturers***' deceptive marketing that influenced a major change in the standard of care and caused the over-prescribing of opioids.[177] Moreover, the evidence at trial has established that professional medical societies, regulatory bodies (like the Joint Commission), and even the West Virginia Board of Medicine and the DEA endorsed prescribing guidelines that approved the use of opioids to treat chronic pain, thereby causing increased prescribing of opioids. Ordering Cardinal Health to pay for reeducating doctors is a complete mismatch of remedy and wrong.

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[175] Trial Ex. DEF-WV-01447 at .00032.

[176] Tr. (June 29) (Barrett) at 106, 186–87.

[177] TAC ¶¶ 372–669 (detailed manufacturer marketing allegations).

The problem of over-prescribing should be remedied by those who caused it. There would be a mismatch in ordering Cardinal Health to pay to remedy problems they did not cause—whether the stigma of addiction, a general lack of awareness about the risks of opioid use, or the safe storage and disposal of opioids.

B. Remedies for Future Addiction

Plaintiffs did not present evidence that Cardinal Health's unreasonable conduct continued after 2012. Any Cabell/Huntington resident who became addicted to prescription opioids after that time, or will become addicted sometime in the future, did not (or will not) do so because of Cardinal Health's conduct. Yet Plaintiffs propose that Cardinal Health pay abatement damages for services designed to forestall or address possible ***future*** addiction. Examples from the abatement plan are numerous:

Plaintiffs seek $48 million for various ***prevention*** programs.[178] But prevention of future addiction, by definition, is not tailored to abating the addiction-related harm caused by Cardinal Health's past actionable conduct. In other words, the Cabell/Huntington residents who became addicted before 2013 are a different population than those residents who became addicted thereafter—and certainly than those who may become addicted in in the future. For example, Plaintiffs seek monies to pay for educating the public that "the evidence for opioids for chronic pain is … limited",[179] presumably to resist doctors' efforts to prescribe them opioids and reduce the risk of future addiction. Such prevention programs may constitute commendable public policy, but the rationale is not remedial based on anything Cardinal Health has done.

[178] Tr. (June 29) (Barrett) at 106–07, 110.

[179] Tr. (June 28) (Alexander) at 37.

Plaintiffs propose reentry programs for individuals released from prisons and jails ("including housing, education, employment," etc.).[180] To be sure, such individuals may be at higher risk of using drugs if not reintegrated into society. But these reentry programs concern the risk of future illegal drug use from the future release of persons who are now incarcerated, and that risk exists independent of Cardinal Health's actionable conduct.

Also having nothing to do with Cardinal Health's past conduct and the population harmed by that conduct are monies for: (1) "enhancing police capabilities to address drug crime";[181] (2) treatment for "individuals on chronic high dose prescription opioids now that may not yet have developed opioid addiction, but will by 2024;"[182]; (3) counseling for "individuals currently that are … living in families where addiction is rampant and their likelihood of developing subsequent addiction is much higher than it otherwise would be;"[183] and (4) services for a "mother who didn't have OUD as of 2018 or 2021, but begins using opioids at some later time, delivers a baby, and that baby has NAS."[184]

C. Remedies That Are Remote From Cardinal Health's Conduct

Plaintiffs' proposed program includes a number of components that are so completely removed from Cardinal Health's conduct to be considered abatement of that conduct or its direct consequences. For example:

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[180] Tr. (June 29) (Barrett) at 95–96, 137–38.

[181] Tr. (June 28) (Alexander) at 141.

[182] *Id.* at 151.

[183] *Id.* at 10.

[184] Tr. (June 28) (Alexander) at 155.

The program includes more than $6 million for workforce expansion and resiliency.[185] Regarding workforce expansion, Plaintiffs would have Cardinal Health pay to "create[] new programs for health care professionals and paraprofessionals."[186] No doubt many small cities across the country would welcome such programs to attract or train more professionals and healthcare workers. But the decline in good jobs in Cabell/Huntington, and with that decline, a drop in the population and shrinkage of the tax base, preceded the opioid crisis by decades and has nothing to do with Cardinal Health's conduct. Programs to expand and improve the local healthcare workforce are a remedy to a problem not of Cardinal Health's making and are not narrowly tailored to the actionable conduct.

Plaintiffs' abatement program also includes $42 million for vocational training and job placement of a more general kind.[187] But that expenditure is not connected to Cardinal Health's conduct; it "entails creating employment opportunities for people with OUD … and supporting employers and the local economy."[188] Even if the job training program were limited to persons with OUD, it would be still be the case that it includes (i) persons who became addicted before Cardinal Health's unreasonable conduct ended, (ii) persons who became addicted after that conduct ended, and (iii) persons who are not addicted, but because "[u]nemployment is a significant risk factor for substance use," ***might*** become addicted in the future. And, in any event, Cardinal Health's conduct has nothing to do with whether Cabell/Huntington residents need education, job skills, or gainful employment opportunities. Again, the remedy is not narrowly tailored to the wrong.

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[185] Tr. (June 29) (Barrett) at 107, 110.

[186] Tr (June 28) (Alexander) at 139–40.

[187] Tr. (June 29) (Barrett) at 138.

[188] Tr. (June 28) (Alexander) at 142.

In addition, the proposed abatement program would pay for measures to improve the competence and expertise of healthcare providers in the identification and treatment of people with OUD.[189] Here, too, the problem (inadequate medical education) is far removed from Cardinal Health's conduct (not blocking suspicious orders), and the proposed remedy is unrelated to the conduct. Similarly, there may be a "need to help the helpers" through programs catered to first responders."[190] But that need presumably exists at all times and in all communities and is not connected to Cardinal Health's actionable conduct.

In the category of "harm reduction," Plaintiffs propose to spend $20 million for services related to illegal drug users.[191] Even if addiction treatment should extend to persons who were primarily users of illegal drugs but for whom prescriptions opioids were allegedly a gateway, it is a step too far from Cardinal Health's actionable conduct to require Cardinal Health to pay for (i) the provision of clean syringes to persons who inject illegal drugs, (ii) education in safer injection practices, (iii) HIV and HCV testing, and (v) medical care for persons who inject drugs, including counseling services.[192] Payments for such services would make a mockery of the principle that remedy in equity "should not go beyond the extent of the established violation."[193]

In the same category of "harm reduction," and extending even farther "beyond the extent of the violation," Plaintiffs propose that Cardinal Health pay for drug-checking services—i.e., checking of the content of illegal drugs.[194] According to Dr. Alexander, Cardinal Health should

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[189] *Id*. at 130.

[190] *Id*. at 48.

[191] Tr. (June 29) (Barrett) at 107, 110.

[192] Tr. (June 28) (Alexander) at 135–36.

[193] *Kentuckians for Commonwealth*, 317 F.3d at 436.

[194] Tr. (June 28) (Alexander) at 135–36.

pay for fentanyl testing strips so that illicit drug users can determine whether their illegal drugs contain fentanyl and (ii) drug checking machines (about which Alexander provided no testimony but which Barrett testified would cost more than $1.3 million).[195]

And Plaintiffs' program seeks $5 million for "surveillance, evaluation, and leadership."[196] This would involve the collection of data "as the epidemic continues to evolve."[197] This is a step too far removed both from Cardinal Health's actionable conduct and from the task of remediation.

These components of Plaintiffs' abatement program and others constitute a plan to treat addiction and a host of other social ills, whatever the cause, not a narrowly tailored equitable remedy.

D. Remedies Related to Root Causes of Drug Abuse

Finally, Plaintiffs' abatement program improperly seeks to charge Cardinal Health with the costs of addressing root causes of addiction—causes that existed before the opioid crisis and that will remain after the crisis is resolved.

Similarly, Cardinal Health is not responsible for the "history of trauma" faced by "women who are commercial sex workers" or the stresses of adolescence.[198] Alexander testified that his discussion with school officials underscored "just how challenged the school system is in managing individuals, adolescents and teens, that may be living in households… that have a high degree of dysfunction."[199] And so he proposed millions of dollars for school programs that

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[195] Tr. (June 29) (Barrett) at 132.

[196] *Id*. at 107, 110.

[197] Tr. (June 28) (Alexander) at 38, 136–37.

[198] *Id.* at 49–50, 62.

[199] *Id*. at 69.

including "screen[ing] [students] for their own risk of opioid non-medical use or addiction."[200] But such relief not only relates entirely to possible future addiction, but also concerns the root causes of drug abuse, not Cardinal Health's past wrongful conduct.

The same is true of Plaintiffs' proposal to spend millions of dollars to remediate the plight of the homeless, because "[i]t's very hard for someone with addiction to get up on their feet if they – if they are homeless."[201] And it is true as well for the $212 million for programs for families and children—programs Alexander justifies because addiction "gets passed down not invariably, but not uncommonly from grandparent to parent to child and so on."[202] Such programs do not reflect tailoring to fit the remedy to the wrong. Instead, these programs are part of a model-community, one-size-fits-all approach to past and present drug addiction.

A federal court's equitable powers do not extend so far. This Court must match the remedy to the wrong, and Cardinal Health's failure to block suspicious orders—conduct that ended almost a decade ago—does not support a $0.6 billion monetary award designed to "restore" Cabell/Huntington to "health" and allow it to "regain its former livelihood."[203]

VI. PLAINTIFFS REQUIRE THE COURT TO SPECULATE

This is not to say that every dollar of the $2.6 billion represents a remedy unrelated to Defendants' allegedly unreasonable conduct. Perhaps there are Cabell/Huntington residents who

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200 *Id.*

201 *Id*. at 67.

202 *Id*. at 49–50 ("[H]aving a parent, a household member with Substance Use Disorder, is a significant risk factor for a child to develop Substance Use disorder."), 66 ("this includes services … to support children that may be living in households where there's a lot of chaos because of the ongoing addiction"), 144.

203 Tr. (June 16) (Young) at 116; Tr. (June 28) (Alexander) at 59. Cardinal Health adopts by reference Parts III, Memorandum of Law in Support of Certain Defendants' Motion for Judgment on Partial Findings Regarding Abatement.

became addicted to prescription opioids before 2013 and who still require services that can be considered narrowly tailored to "match" that conduct. But, for each and every category of remedy, Plaintiffs' abatement experts made no effort to separate the cost of services for addiction developed in the ***past*** from the costs for addiction they predict will develop in the ***future***. In short, there is no evidence that would support a remedial award confined to the cost of services for addressing past addiction attributable to Cardinal Health's alleged wrongful conduct. The Court would have to speculate which it may not do.

VII. PLAINTIFFS' ABATEMENT CLAIM IS TIME-BARRED.

Plaintiffs' purported abatement claim fails for yet another, independent reason: it is time-barred under the accrual rule set forth in *Kermit Lumber*, which provides that a public nuisance claim must be filed within one year of when the alleged nuisance is abated. *State ex rel. Smith v. Kermit Lumber & Pressure Treating Co.*, 488 S.E.2d 901 (W. Va. 1997).[204] In *Kermit Lumber*, the Supreme Court of Appeals addressed when the one-year statute of limitations begins to run in a public nuisance action alleging that hazardous waste at a business site "endangere[d] public health, safety and the environment." 488 S.E.2d at 924. It held that as "long as the arsenic remains on the Kermit Lumber business site in amounts above the regulatory limits and as long as the arsenic is flowing into the Tug Fork River, the harm or nuisance continues and thus, is a continuing (or temporary) nuisance." *Id.* at 925. On that basis, it concluded that the

[204] Plaintiffs have argued that *Kermit Lumber*'s one-year accrual rule "governs here and is dispositive." Pls.' Opp. to Deft.' Mot. for Summary Judgment Regarding Statute of Limitations (Dkt. 288) at 6; *see also id.* at 8 ("With a public nuisance that is temporary (and thus abatable), the statute of limitations does not begin to run *until the nuisance is abated*.") (emphasis added). Defendants respectfully disagree, *see generally* Mem. in Support of Defs.' Mot. for Summary Judgment Re: Statute of Limitations (Dkt. 241), but it is clear that Plaintiffs' claims are time barred even under the special rule of *Kermit Lumber*.

one-year statute of limitations "ha[d] not accrued and will not accrue until the arsenic levels at the Kermit Lumber site no longer endanger 'the public health, safety and the environment.'" *Id.*

Following that logic here, the alleged nuisance—which consists of shipping too many prescription opioid pills into Cabell/Huntington—would remain until the prescription opioid pill levels shipped into Cabell/Huntington by Defendants were no longer "excessive" and no longer endanger the public health.[205] But unlike *Kermit Lumber*, where the evidence showed that the hazardous waste ***remained*** in the environment, Plaintiffs here have presented no evidence that the alleged "flood" of prescription opioids remained in Cabell/Huntington through the start of the applicable limitations period on March 9, 2016.

Plaintiffs filed suit on March 9, 2017 (Cabell County) and January 19, 2017 (Huntington), respectively. Accordingly, the alleged public nuisance must have continued through at least March 9, 2016 to fit within the one-year limitations period. Yet Plaintiffs have failed to present any evidence that Defendants continued to ship an "excessive" volume of opioid pills at or after March 2016. In fact, the exact opposite is true: Plaintiffs have repeatedly stated that Defendants' current suspicious order monitoring programs—***which have been in place since at least 2008***—are irrelevant to the alleged "flood" of opioids at issue in this lawsuit.[206]

Since 2008, Defendants' programs have systematically blocked all orders identified as "suspicious."[207] And, as Plaintiffs' own witnesses have repeatedly admitted, an order that is not

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[205] Defendants deny that their conduct implicates any public right. *See generally* Mem. in Support of Defs.' Mot. for Summary Judgment Re Nuisance (Dkt. 1004).

[206] *See, e.g.*, Tr. (May 14) at 10 ("And, finally, on the relevance standpoint, eliciting testimony about current customers or current [suspicious order monitoring] programs, we fail to see how it has anything to do with the flood of pills that were sold into West Virginia, into this community, giving rise to the opioid epidemic.").

[207] *See, e.g.*, Tr. (June 9) at 13 (Rannazzisi agreeing that "by 2008 every defendant in this case had a policy in place that involved blocking flagged orders").

shipped cannot be diverted or cause any harm.[208] Furthermore, Plaintiffs have not even attempted to demonstrate any wrongdoing on the part of Defendants since no later than 2013. The record evidence, moreover, demonstrates that Defendants' distribution of prescription opioids into Cabell/Huntington began ***rapidly decreasing*** in 2014. Dkt. 1441.1 at 3. Accordingly, Plaintiffs have not come close to showing that Defendants' alleged wrongdoing caused a "flood" of excessive pills that remained in the community as of March 2016.

In short, Plaintiffs have failed to present any evidence of a "flood" of prescription opioid pills that was (1) caused by Distributors' unreasonable conduct and (2) remained present in the community on or after March 9, 2016. Accordingly, Plaintiffs' claims are untimely even under *Kermit Lumber*, and Defendants are entitled to judgment under Rule 52(c).

CONCLUSION

Plaintiffs' story has always been that the wholesale distributors "dumped" opioids in Cabell/Huntington or "flooded" the area with prescription opioids. The evidence has shown that Cardinal Health did no such thing. It filled the orders of local pharmacies that were dispensing opioids as prescribed by local doctors pursuant to the prevailing standard of care. In so doing, Cardinal Health was responding to the same impulse that led the DEA to raise the opioid quota annually for fifteen years—i.e, make sure that patients have the medications their doctors have prescribed for them. Plaintiffs have not met their burden to prove that Cardinal Health acted unreasonably or that its conduct was the cause-in-fact or proximate cause of harm to Plaintiffs, and the unprecedented abatement relief they seek is beyond the equitable power of the Court to award.

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[208] *See, e.g.*, Tr. (May 26) at 208 (Rafalski agreeing that blocking an order is "what prevents diversion from occurring"); Tr. (June 9) at 13–14 (Rannazzisi acknowledging that a blocked order "can't go downstream" and therefore "can't be diverted").

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Respectfully submitted,

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